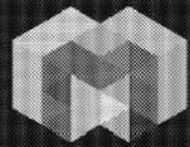


PSJ2 Exh 88



Mallinckrodt
Pharmaceuticals

Steve Carchedi
St. Louis, MO

4/17/2013
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- ▶ Executive Summary
- ▶ Market Insights
- ▶ Vision & Strategic Imperatives
- ▶ Critical Success Factors
- ▶ Sizing the Revenue Opportunity
- ▶ Sales Force Sizing Options
- ▶ Launch Governance, Structure, Timelines
- ▶ Next Steps



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Executive Summary



**MNK-795 will drive stakeholders to rethink acute pain treatment and abuse deterrent properties.
Demonstrate the unmet need around acute pain by humanizing the issue.
Establish MNK 795 as a new standard in acute pain management.**

➤ **MNK-795 Has ~\$250M US Potential Peak in the Opioid Market**

- One of the first new brands in the acute pain combination opioid market in the past 20 years
- Controlled-release analgesia and abuse deterrence properties

➤ **The Acute Pain Market Is Ripe with Opportunity**

- The opioid combination market is poised for innovative options
- Global pain market over \$20B; The largest segment is the acute pain segment
- Few branded competitors and limited number of drugs in development

➤ **MNK-795 Addresses the Market Needs**

- Quick onset, relief within 30 minutes of dosing
- Controlled release, which helps patient's sleep through the night without waking
- Abuse deterrent properties, which meet the FDA guidance; label to include data

➤ **MNK-795 Will Give HCPs and Allied Stakeholder's Reason to Pause**

- 30+ year habitual prescribing will be challenged due to recognition / appreciation to **assess and treat the patient and greater abuse problem**, as opposed to treating the pain (eg, Percocet 1-2 tabs, q4-6h)

➤ **Mallinckrodt Will Realize Vision as the Market Leader in Pain Management**

- More than 20 years experience in marketing pain drugs and a track record of successful collaborations

MNK795: Organizational and Product Readiness

Executive Summary



- MNK795 is recognized as a significant source of revenue and is a critical element to the success to the New Mallinckrodt
- Significant sense of organizational urgency and alignment for launch preparation / readiness
- MNK795 is the enabler for Mallinckrodt to be recognized as a leader in pain management among the broader healthcare community using the AcuForm® platform with ADT (Abuse Deterrent Technology)

Opportunities

- Create a new market for the management of Acute Pain by changing a well established treatment paradigm
- Leverage the AcuForm® gastro-retentive delivery platform to transform a well established market
- Create the optimal USPI to drive successful commercialization and market differentiation
- Execute comprehensive advocacy plan with key stakeholders (HCPs, Regulators, Policy)
- Broaden MNK-795 clinical utility by extending the clinical development program
- Expedite Phase IIb/IV / HOPE / Level 4 ADT real-world study with closed model HMO
- Innovate our approach to commercial scale up activities

Risks

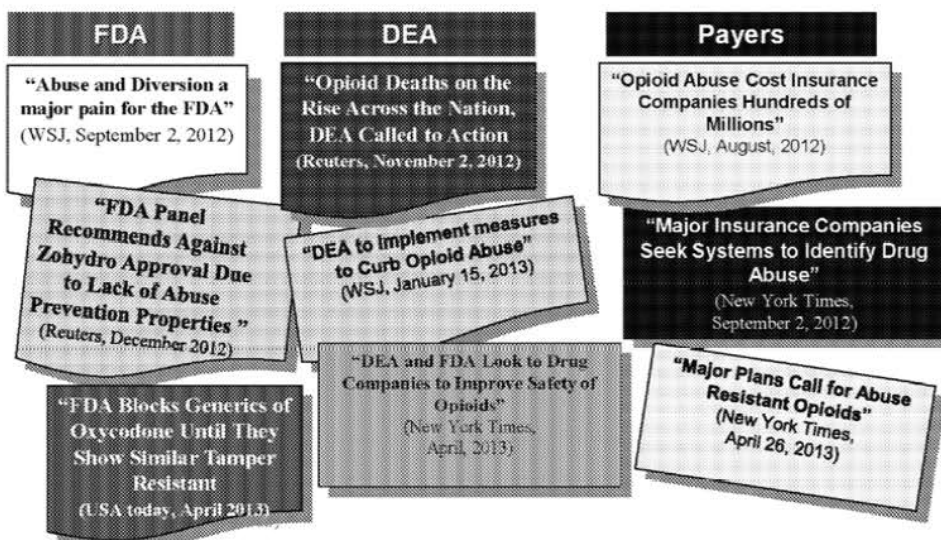
- Intellectual Property Horizon (Timeline)
- Label / Value Proposition (FDA)
- Market Access (Timing / Level / Cost)
- Commercial Structure (Timing / Investment)
- Clinical Data Generation (Timing / Investment)
- ADT Capabilities / Level 4 Validation (Timing / Investment)

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Market Needs in Pain: Prevention of Abuse and Diversion

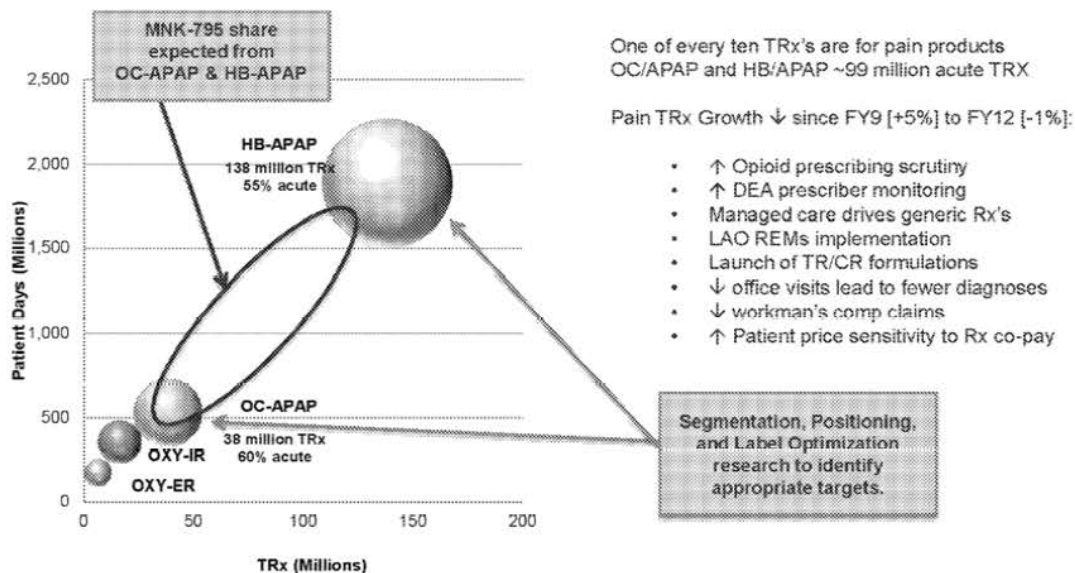
In the past 10 years, the pharmaceutical industry has been responsible for 47 instances of unlawful promotion, leading to >\$5B in fines and settlements*



Institutional Stakeholders are calling for rapid solutions to opioid abuse and regulators are requiring that new pain drugs address abuse and diversion

Assumptions Page

Acute pain Rx's > 100 million; market facing headwinds; MNK-795 share anticipated mostly from existing generic OC-APAP



Source: IMS NSP and NPA through September 30, 2012

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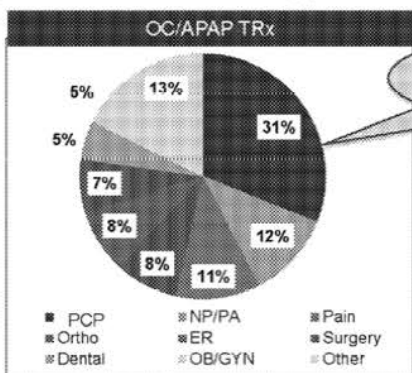
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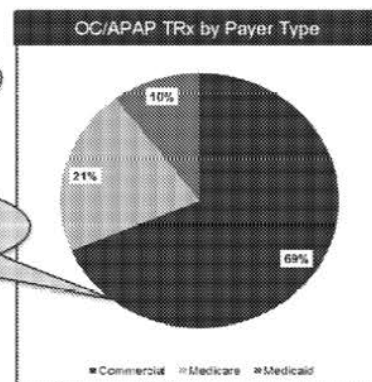
Large # of PCPs; specialists are more productive writers; 69% of acute pain TRx paid by commercial plans

08/2011-07/2012	Pain	Primary Care	Ortho	Surgery	ER
# HCPs	22 K	238 K	20 K	40 K	30 K
Acute Rx	5 MM	18 MM	3 MM	3 MM	3 MM
Rx/HCP	172	65	142	65	96
AVG Days of Therapy	25	17	10	7	4



Attitudinal/behavioral segmentation necessary, >230k PCP/NP/PA writers!

Patient price elasticity/managed care research to maximize access.



Sources: IMS Xponent® PlanTrak™ Monthly data, from August 2011 through July 2012.

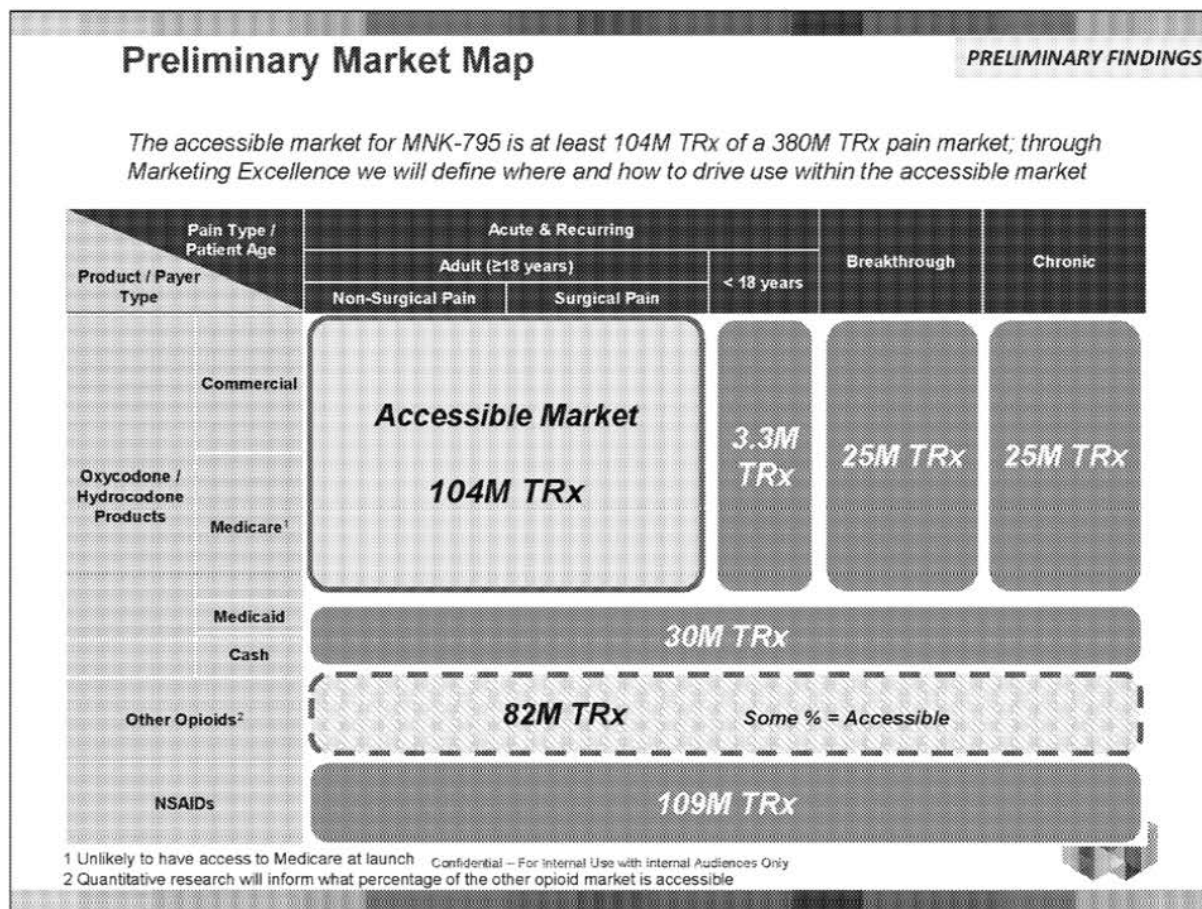
Market=All OC/APAP TRxs. No assumptions were made to determine if the TRx was chronic, acute, etc.

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104M TRx are accessible to MNK-795

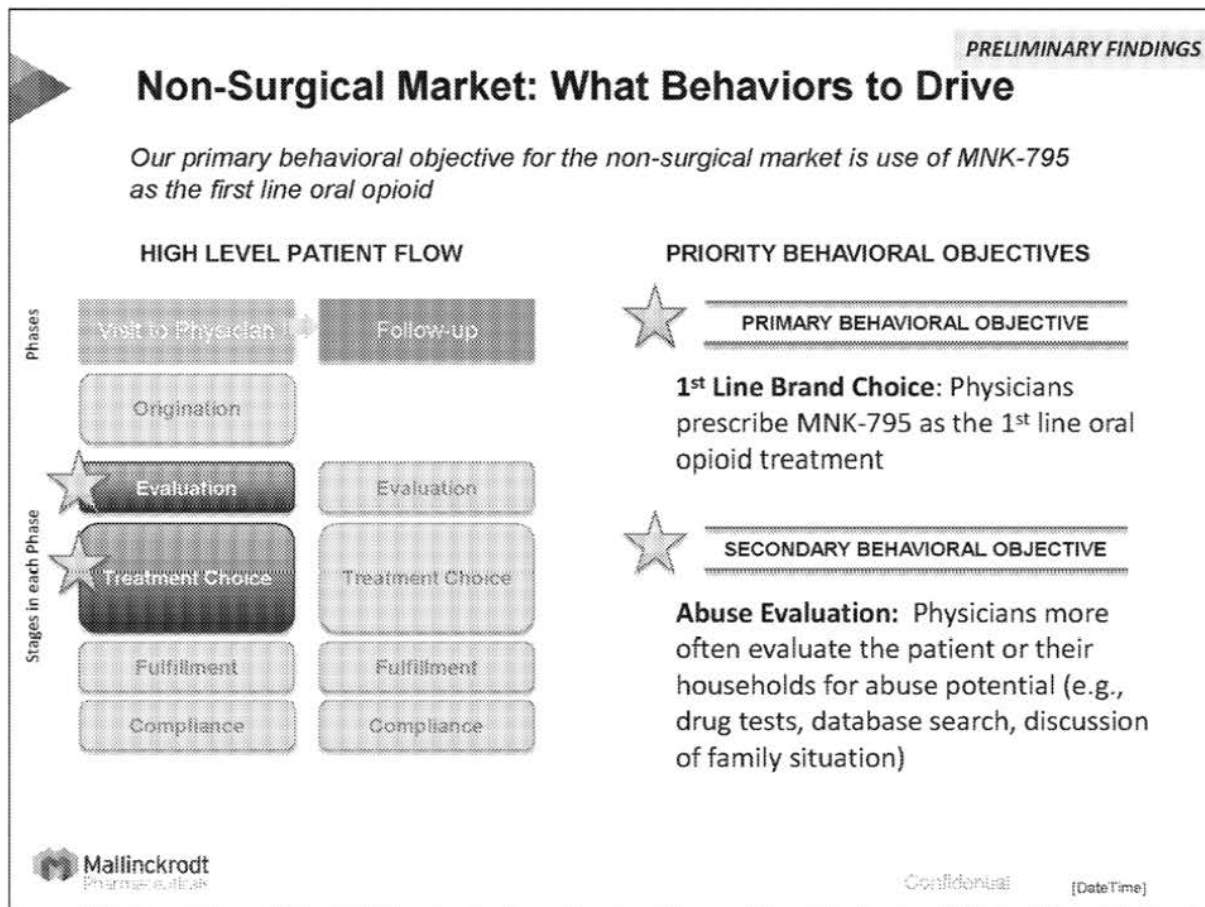
Defining the accessible market as TRx that are:

Consistent with our expected label (e.g., acute pain, adult patients)

Likely reimbursable (e.g., covered by commercial insurance)

Currently for products we believe we could steal share from (e.g., combo opioids)

Actual target market is being defined through segmentation work (in progress) and is likely to be smaller than total accessible market (e.g., we might not pursue all surgical patients)



In thinking about what behaviors we want to drive, we have thought about the non-surgical and surgical markets separately

For the non-surgical market we believe the greatest opportunity is in driving first line use of MNK-795

This is the largest opportunity within non-surgical market; only 36% of patients receive a follow-up script

Additionally, there is limited switch at follow-up: only 25% of all follow-up Rx are for a different compound

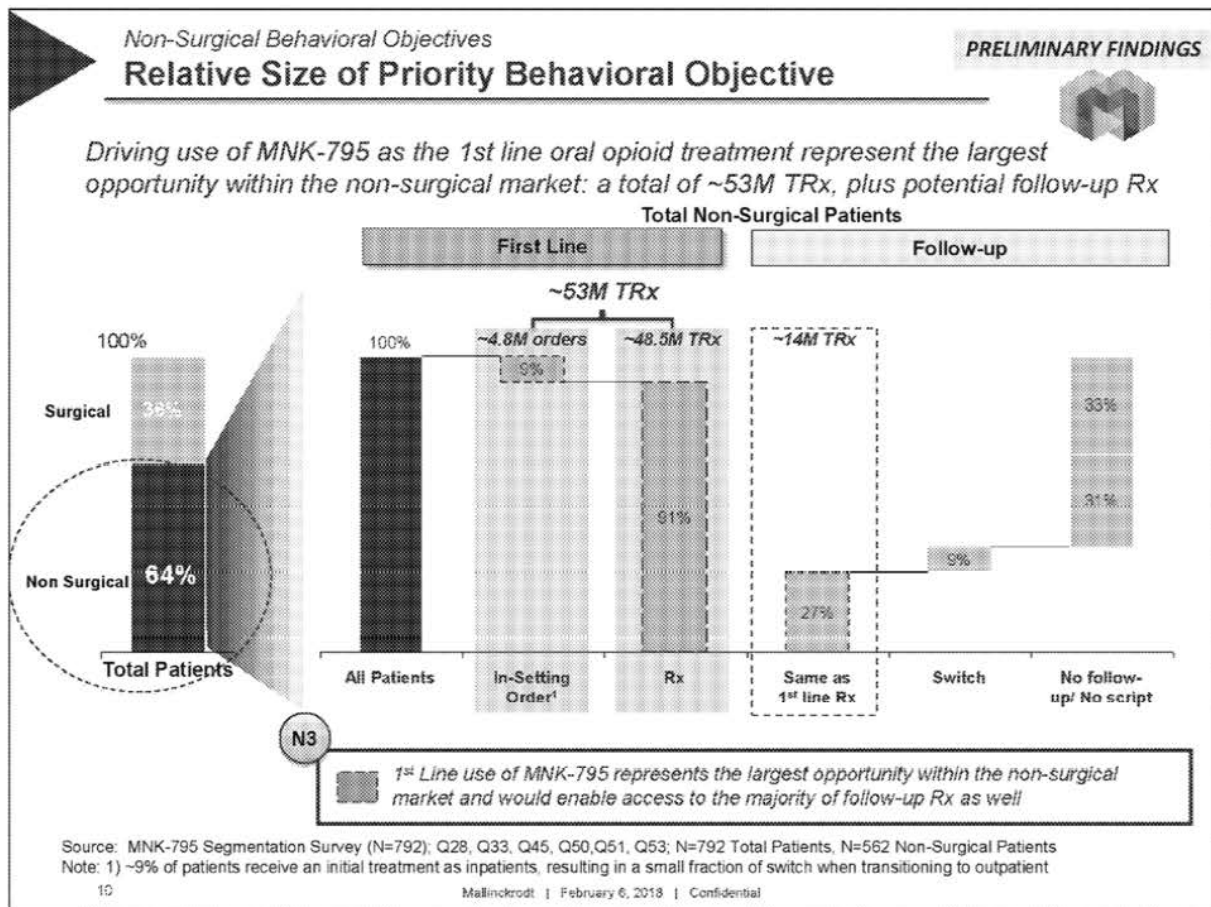
A secondary objective is to drive greater abuse evaluation of both the patient and their household

Increasing the frequency of specific abuse evaluation behaviors is positively correlated to likelihood to prescribe MNK-795

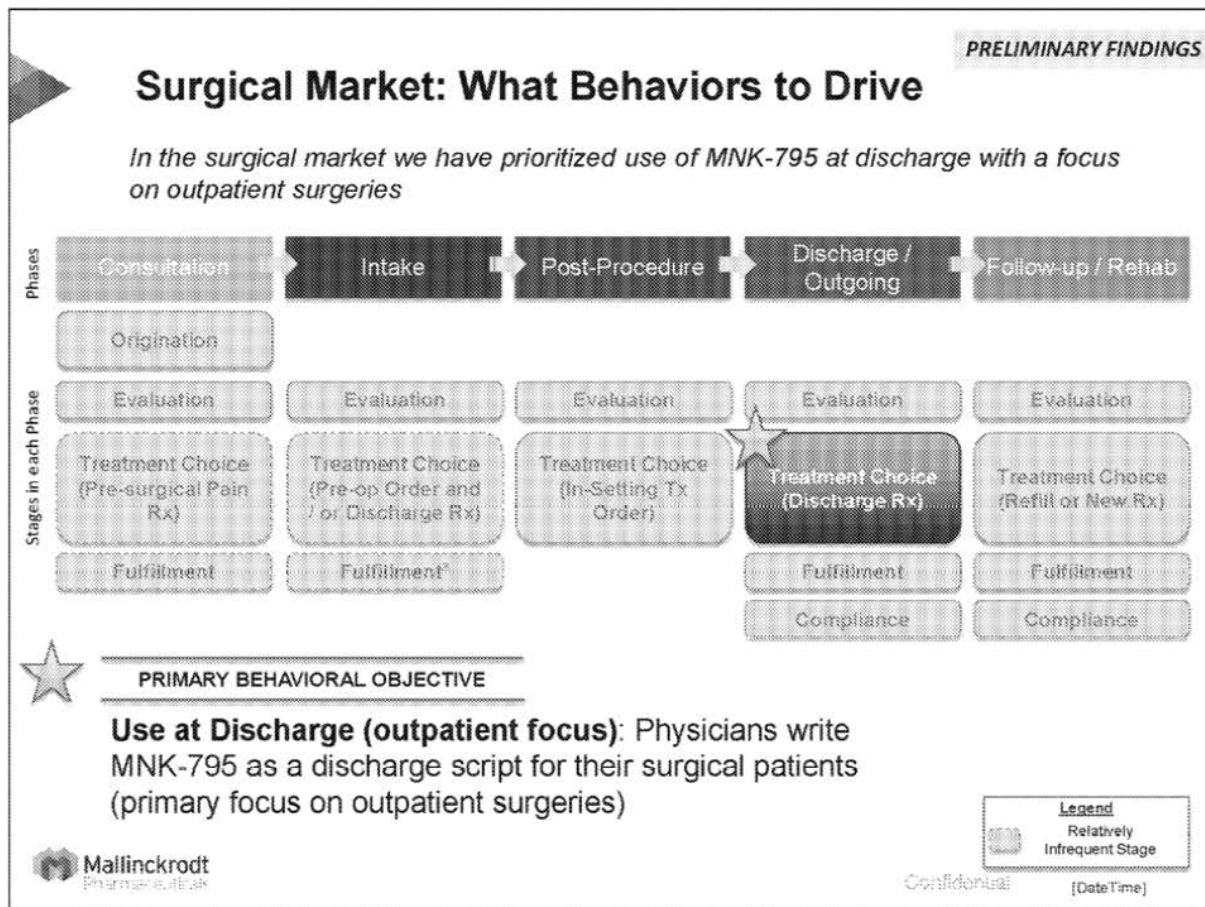
Physicians report concern for abuse potential and risk addiction for ~30% of their patients

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For the surgical market we believe the greatest opportunity is in driving physicians to write MNK-795 as the discharge Rx for the outpatients

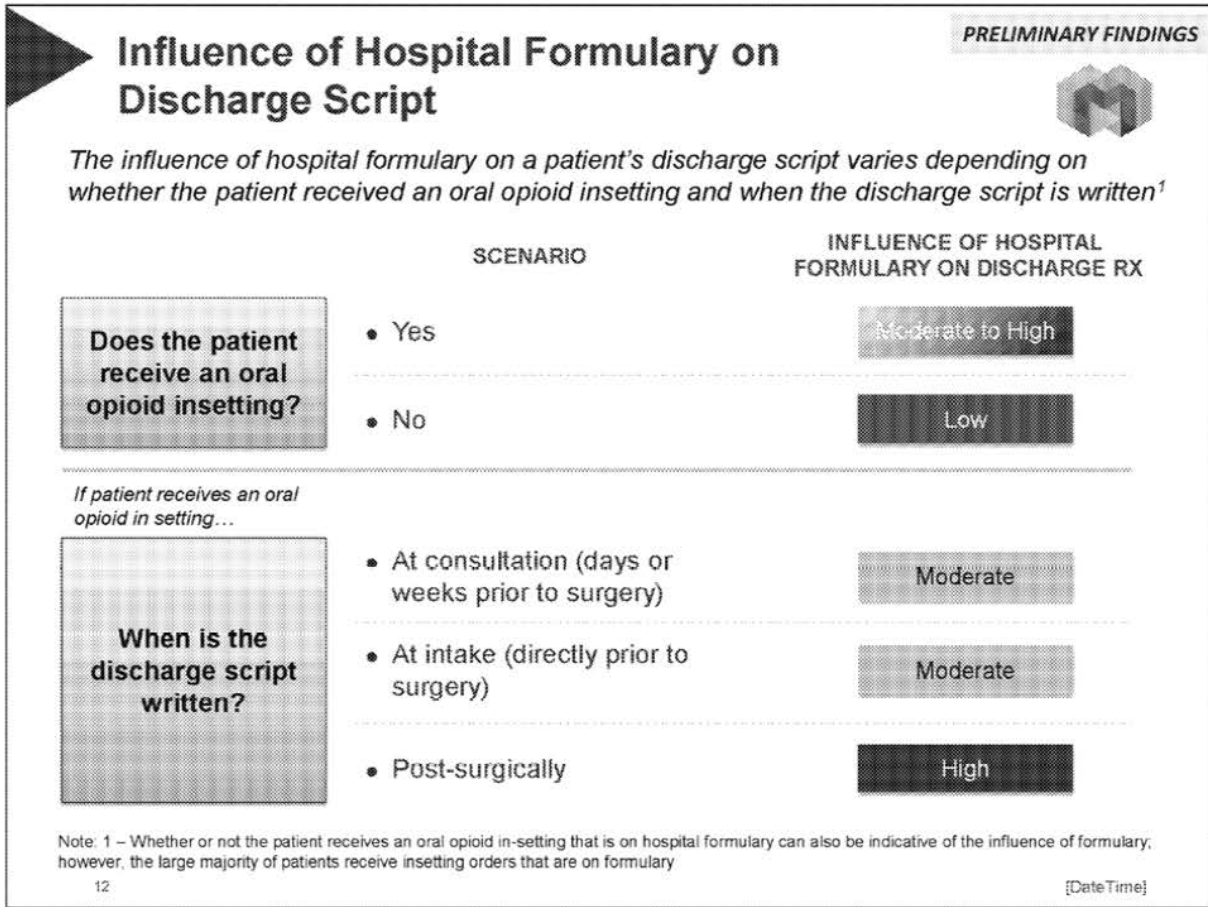
Why outpatient, not inpatient?

The challenge in the surgical setting is that patients typically stay on whatever product they get put on insetting and formulary almost always dictates this choice, this is particularly true in with inpatient surgeries

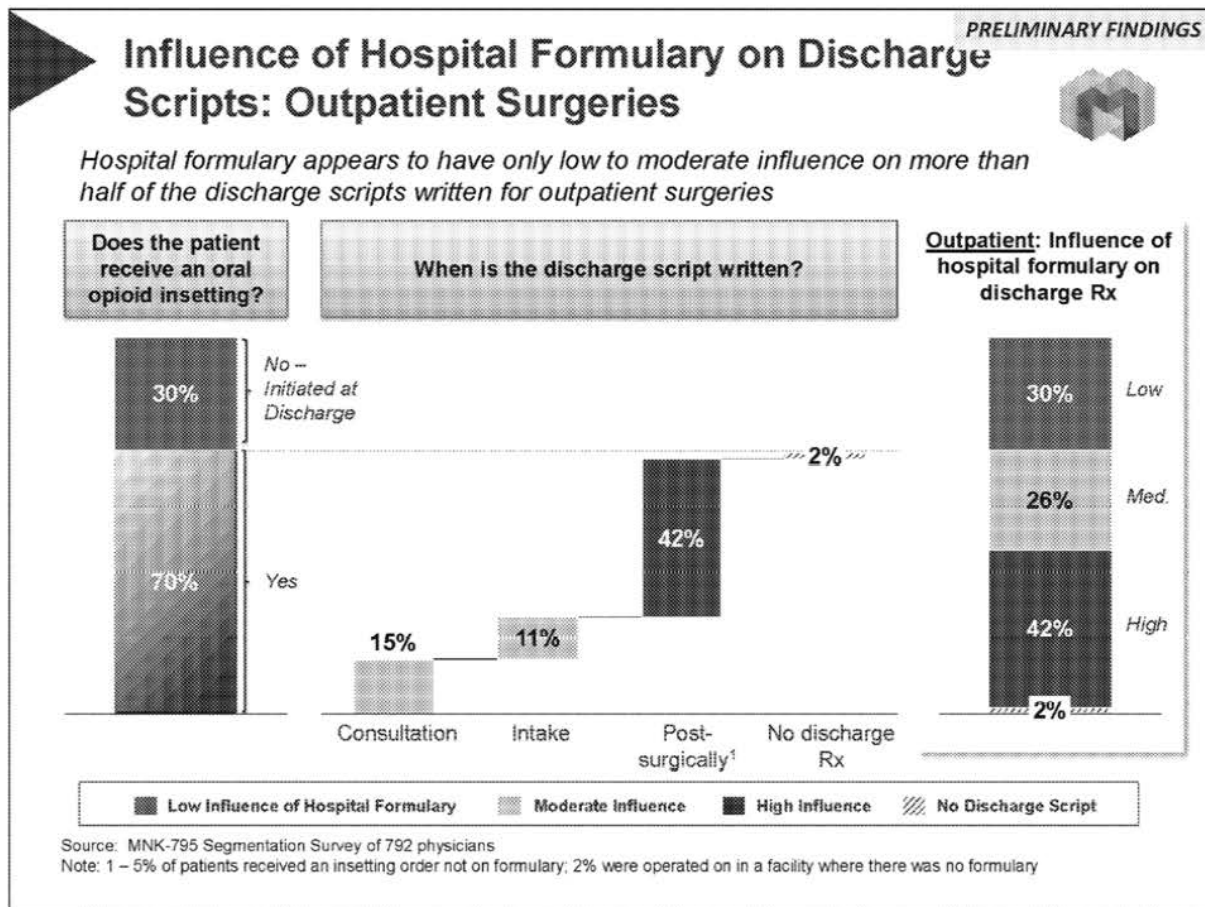
However, formulary appears to have a much smaller impact on outpatient surgeries as ~25% receive their discharge Rx before surgery and another 30% of patients receive nothing insetting

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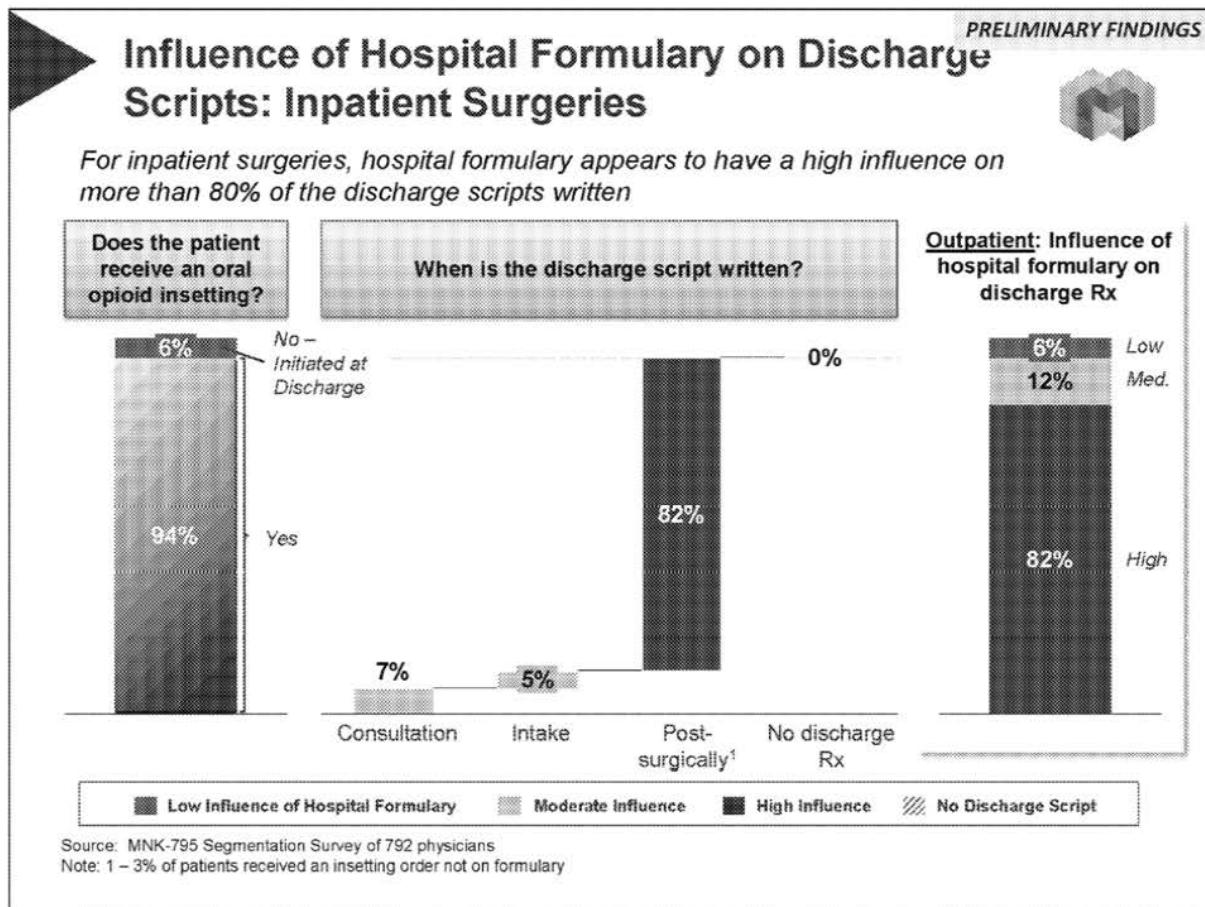
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Hospital formulary has high influence in setting



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Emerging Insights from Research to Date

Research to date has surfaced a number of important opportunities and challenges MNK-795 is likely to face in the market place

- 1 Many physicians **recognize the value of an immediate release, long-acting opioid** for acute patients; **also value the flexibility of multiple dosage strengths and the patient control of PRN dosing**
- 2 Physicians not accustomed to interpreting product profiles for controlled release drugs. **Accustomed to dosing oc/apap as 5mg oxycodone 1-2 tablets Q6, unaware of oxycodone dosing over 12 hours. Mistakenly perceive a 15mg oxycodone Q12 dose to be a "strong Percocet".**
- 3 Abuse potential is widely recognized. **Concern for abuse appears more likely to be stronger driver of treatment for non-surgical pain**
- 4 There **significant "path dependency" in the surgical setting** with many patients staying on the oral opioid they are stabilized on insetting. **However, this path dependency appears easier to overcome with outpatient surgeries**

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Salient themes from research to date (which has included both quantitative and qualitative studies)

HCPs find the immediate release component and long-acting nature appealing; some believe this will help their patients get ahead of the pain;

Physicians appreciate flexibility of multiple dosing strengths; they appreciate the ability to titrate patients up or down as needed

Many physicians appear to mistakenly perceive MNK-795 to be a "strong Percocet" as the product is a higher strength than they typically use (81% of Rx are for 5 mg); this creates the risk that the product could be used in patients whose pain is too severe for the product

There is a high awareness of abuse among HCPs; "Red Flags" can lead to suspicion of abuse when treating acute pain patients, doctors may avoid opioids or Rx fewer tablets; however, abuse deterrence is a relatively low priority for acute patients, particularly those with post-surgical pain

There appears to be significant "path dependency" in the surgical setting, meaning if a patient receives a product insetting, they are likely written the same product at discharge. However, this appears to be less of an issue in outpatient surgeries where patients more often are written a discharge Rx before surgery or receive nothing in setting

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Emerging Insights from Clinical Advisory Boards

Surgical and Pain Specialists Commercial Advisory Boards identified a number of important opportunities and challenges MNK-795 is likely to face in the market place

- 1** Most acute pain patients have pain lasting longer than 12 hour/day; initial prescription 2-4 weeks. Physicians typically selects and prescribes one molecule, **Oxycodone is more often preferred** due to perceived potency, clinical benefits and multiple options.
- 2** **Reduced peak-to-trough variance could alleviate the AEs** /lack of effect related to the highs and lows associated with Percocet dosing. Without clearly understanding PK, **15 mg dose may be perceived as too high a starting dose for some patients.** Majority agreed that MNK-795 was equivalent to Percocet and **could provide an advantage in dosing**
- 3** **Bunionectomy data are not relevant to clinical practice**, however **most felt the data demonstrated similar efficacy to Percocet.** Wanted **insights on supplemental analgesia** in a clinical setting. **Concern that MNK-795 label does not allow for titration/tapering.**
- 4** Clinicians are **not routinely concerned with potential misuse or abuse of opioids by acute pain patients.** Abuse and HAL data requires clarification regarding benefits to intended clinical population and society

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HCPs find the immediate release component and long-acting nature appealing; some believe this will help their patients get ahead of the pain;

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Segmentation HCP Sampling Plan & Recruiting

Recruitment Criteria for Survey:

- US-based Physicians
 - PCP/ORS/GS/Pain Mgt/EM specialty.
 - 70%+ (30+ for ANES) time spent treating patients in private practice.
 - Treat 200+ total patients in average month.
 - Treat 20+(PCP)/28+(Other specialties) moderate to severe acute pain patients in average month.
 - Full time practice; in practice 2-35 years.

Analysis Detail:

- 792 web survey interviews conducted from May 16 – June 4, 2013.
 - Each online survey lasted roughly 60 minutes.
 - Respondents viewed a product profile blinded as Product X.
 - Red = significantly higher than that letter.
 - Confidence level = 95% unless otherwise noted.
 - Respondents completed patient chart pull exercise for one moderate to severe acute pain patient 18 years or older seen in last 30 days.

Completes by Target Specialty

Primary Care Physicians (PCP)	Orthopedic Surgeons (ORS)	General Surgeons (GS)	Pain Management (PM)*	Emergency Medicine (EM)	Total
350	152	53	126	111	792

*Pain Management segment includes: Pain Management, Physical Medicine & Rehabilitation, and Anesthesiology physicians.

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Key Segmentation Findings: The MNK-795 Story

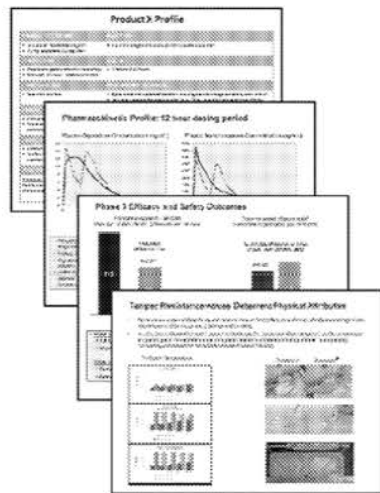
- **MNK-795 is received positively with an opportunity in the moderate-to-severe acute pain market.**
 - Unadjusted patient share for MNK-795 is close to one in five (18.3%) moderate-to-severe, acute pain patients.
 - Only 1 in 10 target (12.9%) physicians estimates to be a non-user
 - Physicians estimate they are somewhat likely to prescribe (6.4 out of 10).
 - Efficacy (39.2%) is the top advantage; controlled release over 12 hours is second (21.0%).
 - The benefit most likely to be ranked #1 is "Has smoother controlled release with less peaks and troughs" (29.9%).
- **Based on treatment approach and population size, MNK-795 opportunity lies more with non-surgical physicians.**
 - Estimated size of potential patient types: post-surgical pain patients (40.4%).
 - Estimated size of potential patient types: non-surgical pain (86.4%).
- **Abuse is perceived as a problem, but most currently available technologies are not perceived as the solution.**
 - Physicians (7.9 out of 10) are very concerned about their patients abusing opioids by taking too many pills.
 - Physicians suspect up to a third (30.2%) of their patients are abusing or are addicted to their pain medication
 - Tamper resistant formulation is the 5th highest advantage (18.3%) and abuse-deterrent is the 7th (16.1%).



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Summary of Stakeholder Interviews

MNK795 profile, and additional product attribute slides were shown to each interviewee for impressions



Interviewees were told about a hydrocodone/APAP product (MNK155) with similar features

Payers Reaction to MNK795 Profile

- **Accepted efficacy**, though product profile and comparison to placebo did raise questions
- Use of **supplemental analgesia is standard** practice in trials for “ER” opioids, but majority wanted additional data on what was used & when
- **Intrigued by HAL data, but not likely to influence coverage** without outside pressure from MD prescribing or government mandates
- Acute and chronic pain are loosely defined categories for **payers**, who **typically apply the same management philosophy to all pain products**

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Implications on Strategy:

Their current position on coverage assumes comparable pricing and formulary status.

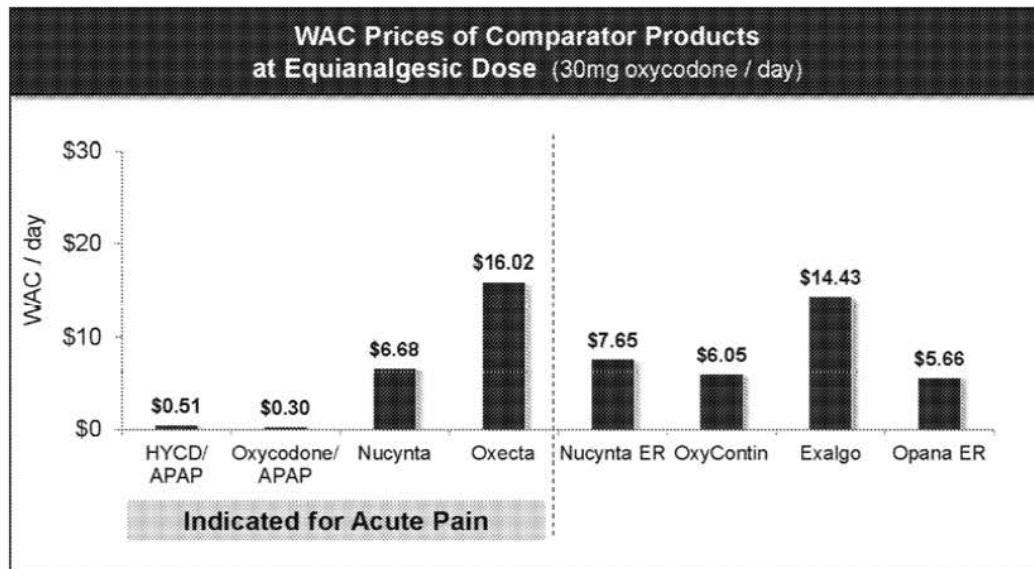
Some products have been able to attain Tier 2 status or Tier 3 without restrictions through contracting.

Payers buy the efficacy of 795, see supplemental analgesia as a standard of care, are intrigued by HAL and say they typically apply the same philosophy to all pain meds when it comes to formulary inclusion.

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Comparator branded opioid products range in WAC price from ~\$6-8 per day at equianalgesic dose



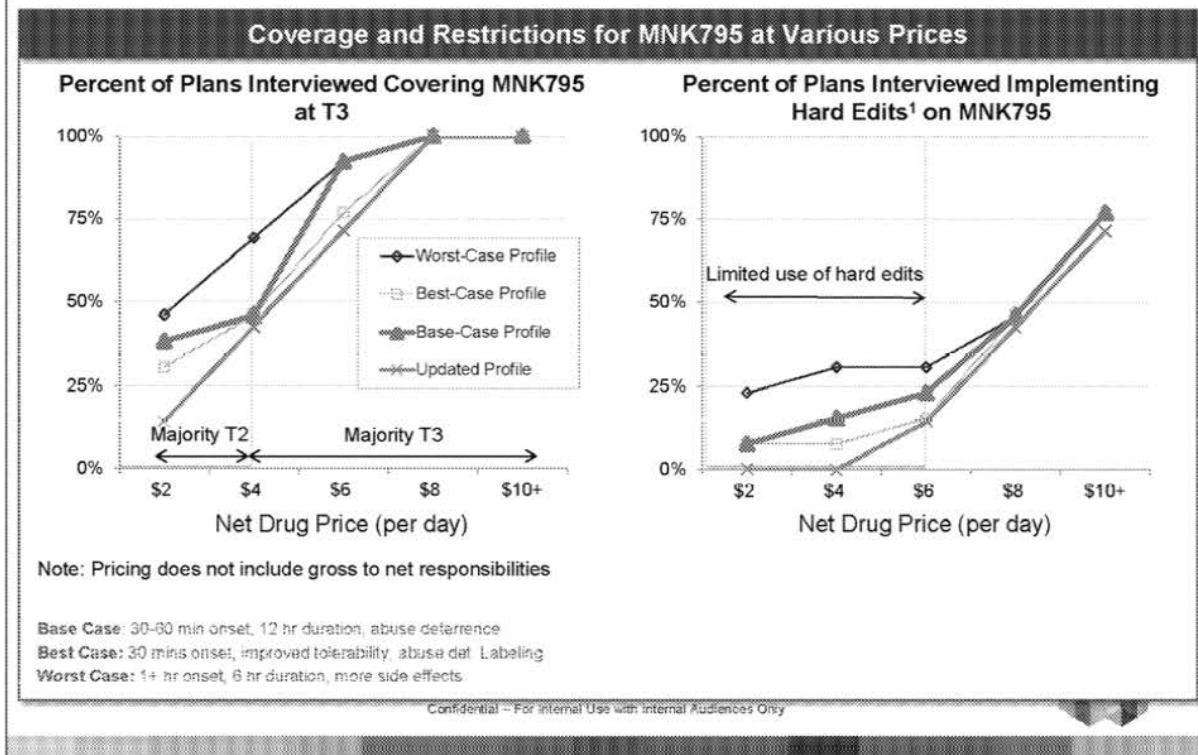
Note: pricing compared to the cost of the real daily consumption of comparator products was also considered

Source: PricePoint Rx (Oct. 3, 2012); UpTo Date; IMS (2012-4Q)

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There is a higher tolerance for price for Tier 3 with no edits vs. Tier 2 with no edits.



The Cost vs. benefit evaluation revealed that there is a significant increase in utilization for products that are placed on Tier 3 with no hard edits.

Tier 2 coverage is likely to require significant rebates, real world data showing reduction in abuse, medical costs etc. Even at \$2/day, some plans say they will not cover 795 at Tier 2.

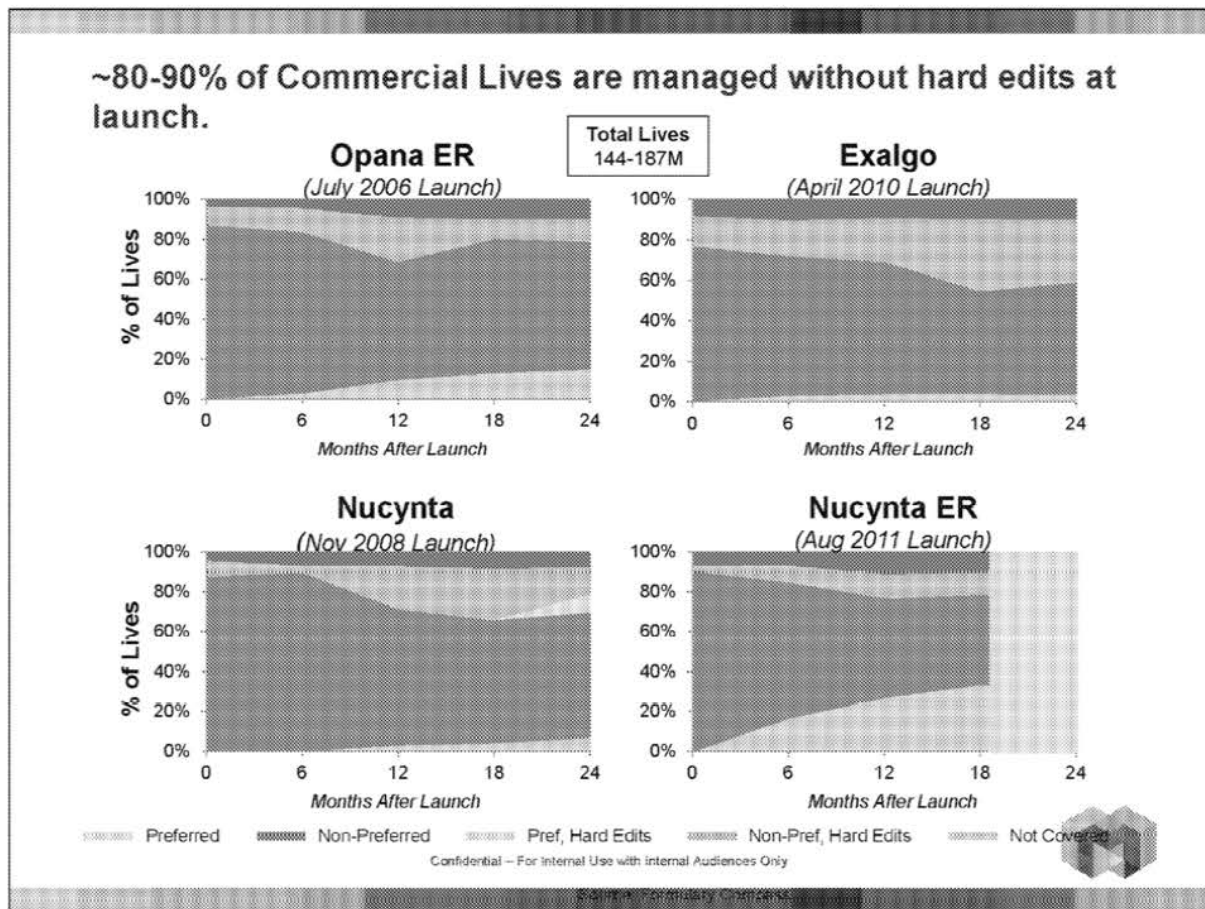
At \$6/day 50% of plans will institute hard edits – prior authorizations and step therapy.

Our launch contracting strategy will likely focus on large plans willing to remove hard edits.

Our ongoing analysis will identify plans for which attaining preferred status (Tier 2 or lowest branded tier) is a significant advantage.

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The Commercial Payer is open to covering the product at launch with little to no restrictions.

Although 80-90% are covered at launch, management with hard edits becomes more common at 6-18 months as seen by the increase in yellow and light blue over time.

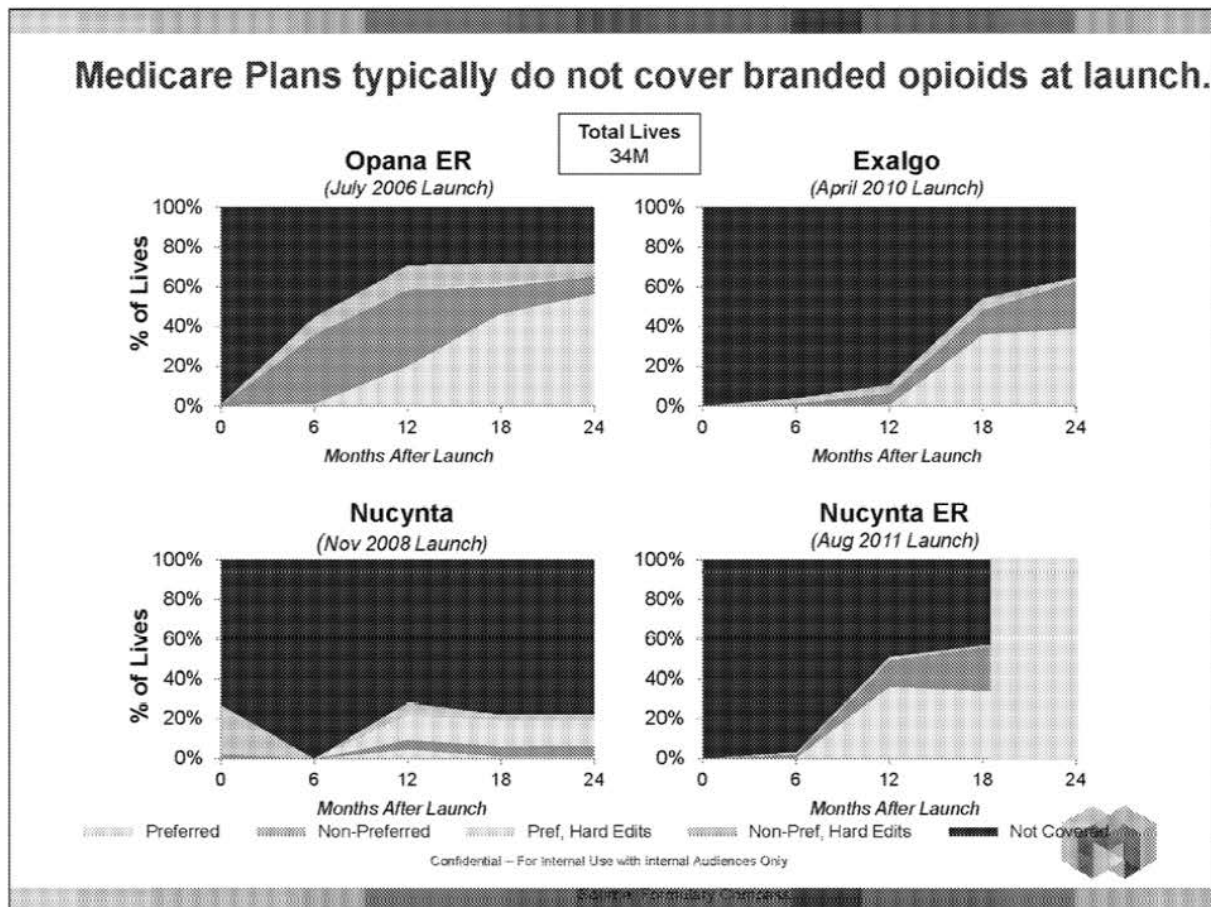
In recent years, plans are putting more restrictions on products at launch. e.g. the launch of Opana ER in 2006 had better coverage than Exalgo at launch in 2010. Nucynta ER is an exception to this, likely because IR was already established in the market place.

As many as 45% of lives may be managed without restrictions after 18 months.

Preferred status is more easily attained by NEW formulations of established opioids (e.g. Nucynta ER).

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To put the Medicare opportunity into perspective, it is important to know:

Medicare Part-D plans have a definite time period to review new products (90-120 days).

The benefit year also highly influences the ability to get a product assessed for formulary.

For example 2014 formulary decisions were made in April 2013. The next review cycle for MNK-795 will be in April 2014 for the 2015 benefit year unless we get the Part-D carrier to consider a mid-year add which will likely require a significant discount

Looking at these 4 brands, you can see the contrast from the prior slide with commercial. Medicare plans typically do not cover branded opioids at launch.

However, some plans will offer a medical exception

Branded products must be reviewed within 6-12 months for initial formulary placement.

It appears that preferred status is more commonly granted when they decide to cover the product.

Many payers only place 1-2 branded pain products on formulary

Once a decision to cover the product is made, hard edits not typically assigned

Medicaid plans are highly restrictive, typically placing restrictions on or not covering branded opioids

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Additional secondary analyses helps to refine market access strategy, priorities and model development.

Analysis	Purpose
Segmentation & Formulary Coverage Over Time	<ul style="list-style-type: none"> ▪ Examine formulary coverage of analogous pain products over their first 24 months post launch ▪ Determine timeliness of payer decision-making and default coverage during product launch phase
Patient Abandonment & Claims Rejection	<ul style="list-style-type: none"> ▪ Evaluate abandonment and rejection rates across a set of products ▪ Inform contracting objectives and benefit of Tier 2 vs. Tier 3 coverage
Effect of Coverage on Utilization	<ul style="list-style-type: none"> ▪ Measure impact of formulary coverage on utilization across plans

*OxyContin used for segmentation component only as OxyContin Formulary Compass data was limited to its current coverage
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A broad basket of opioids both long acting and short acting indicated for acute pain or chronic pain or both were examined for their formulary coverage over time, patient abandonment of the script at the pharmacy, plan rejection rates and why, and finally for the effect of coverage on utilization over time. These analysis are feeding our decision support tool to guide or segmentation and prioritization of accounts.

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SWOT Analysis

Work in Progress

Strengths

- Similar efficacy and tolerability vs Percocet
- Fast onset of Percocet – longer duration
- Avoids 'highs and lows' and fluctuations
- Improved risk profile for misuse and abuse vs. Percocet and other combo opioid products
- Unique, proprietary delivery system
- Abuse deterrent characteristics/data (in vitro and in vivo)

Weaknesses

- Branded product in a generic dominated market
- Limited efficacy data to differentiate from other products
- ER products usually associated with chronic pain
- Longer duration of APAP exposure may be associated with perceived increase toxicity risks
- Limited dosage strengths
- Fixed dosing

Opportunities

- Large acute pain market with unmet treatment needs (limitations of IR formulations)
- Low APAP dose over longer duration can reduce risks of dose related toxicities
- Leverage government legislators to influence payers related to abuse
- Differentiation through ER/LA REMS
- Inclusion of HAL and in vitro data in label based upon OxyContin precedence

Threats

- Large pool of patients that "churn" every 30 days
- Price per day at a level payors/patients are willing to pay may fluctuate with economic environment
- Future competitive launches (NCEs, abuse-deterrent technology, etc.)
- New single-entity opioid competitive entrants likely to message against APAP

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Draft Positioning Statement

PRELIMINARY VERSION
TO BE TESTED
(one of four)

To: HCPs who routinely prescribe Percocet

MNK-795 is: the first and only controlled-release oxycodone/APAP product

That: provides fast-acting and long-lasting pain relief without concerns about abuse

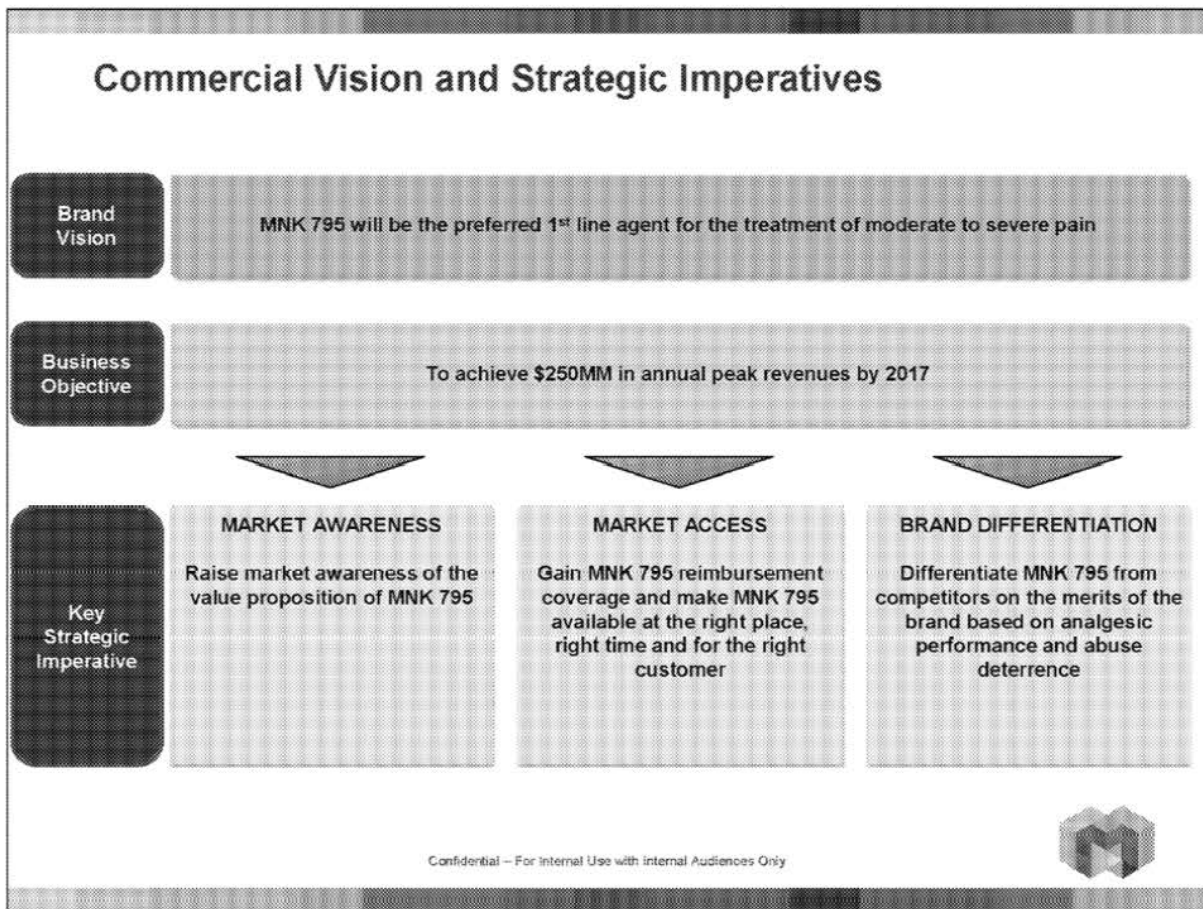
Because: it's formulated with unique physical properties that yield an improved pharmacokinetic profile

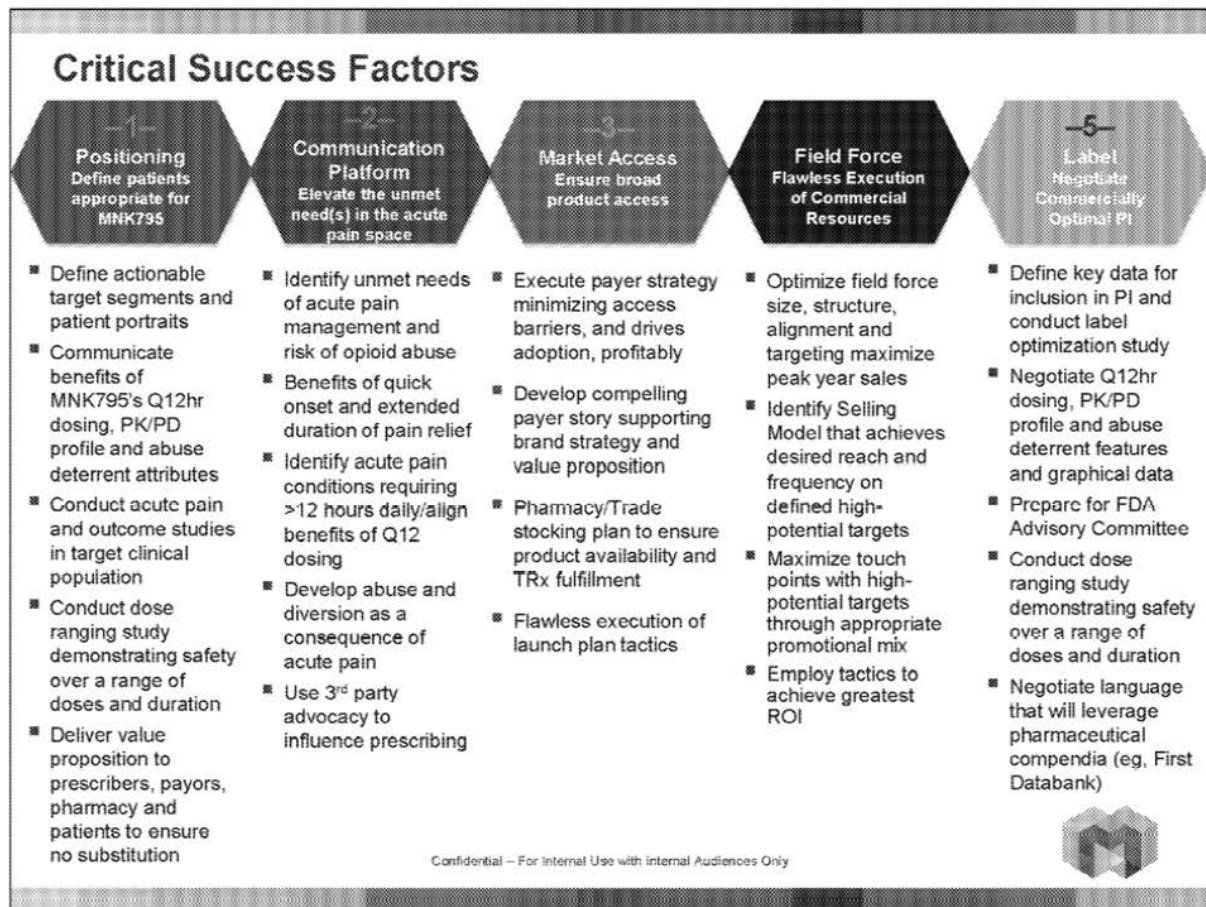
So that: they can confidently provide a superior treatment that is more responsible to patients and society

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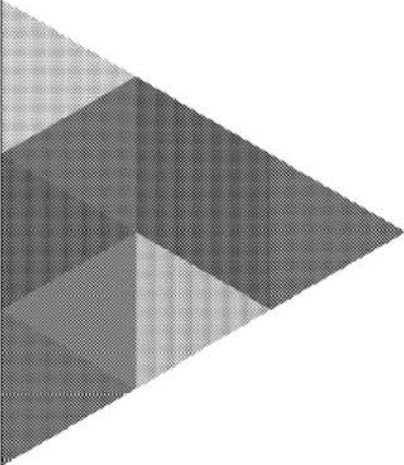


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Positioning



Positioning
Define patients
appropriate for
MNK795

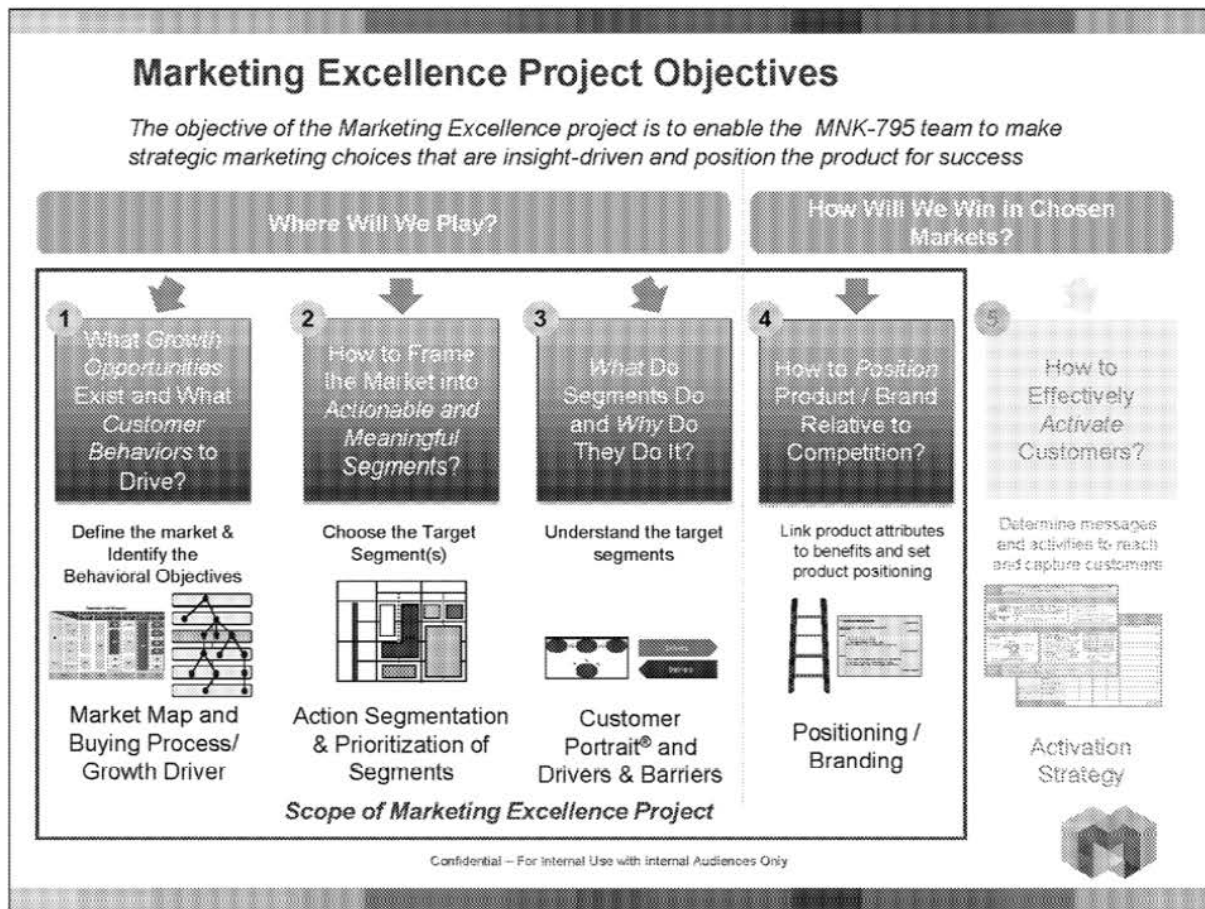
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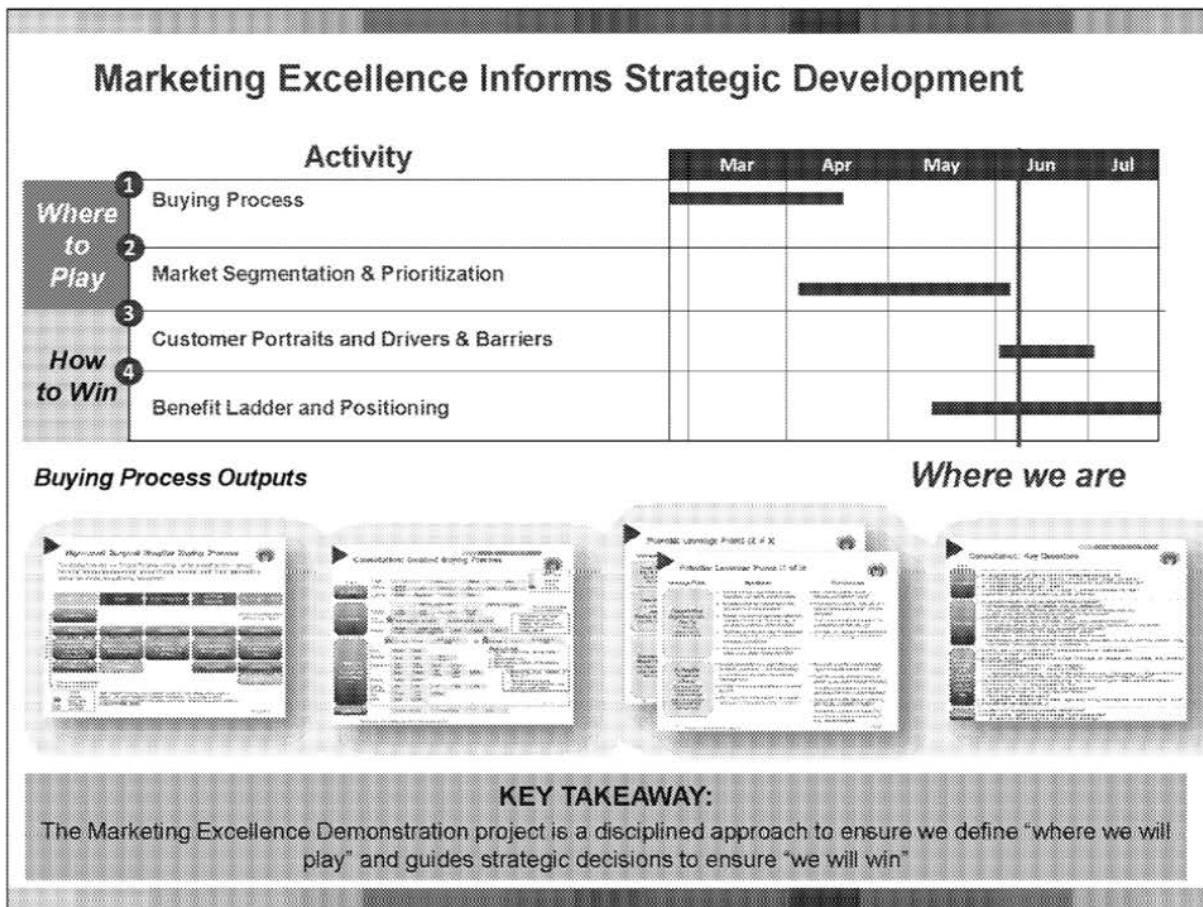
Marketing Excellence project is focused on 4 key strategic marketing choices

Choosing where to intervene in the market and what customer behaviors to drive

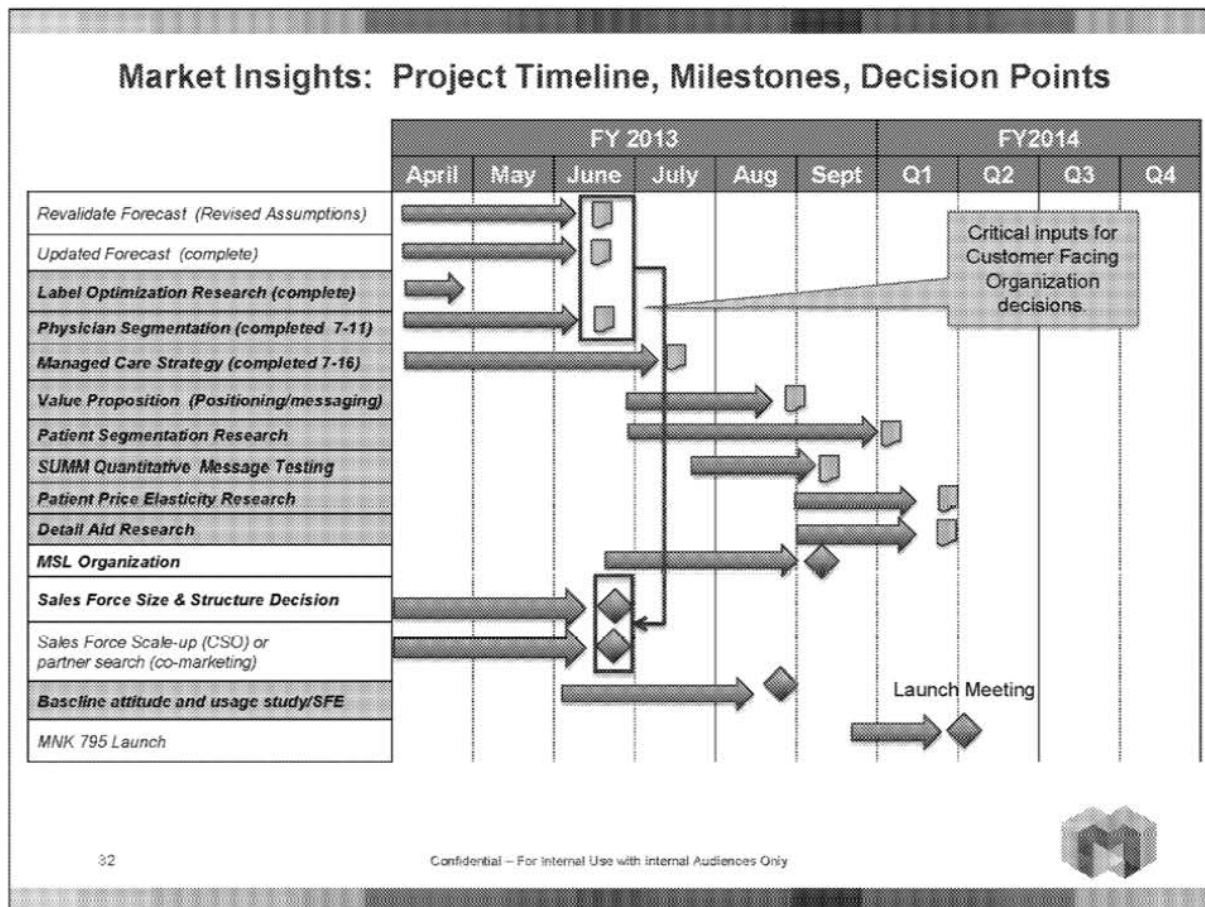
Framing the market and choosing target segments to disproportionately pursue

Identifying critical drivers and barriers to use of MNK-795 and product benefits that could overcome them

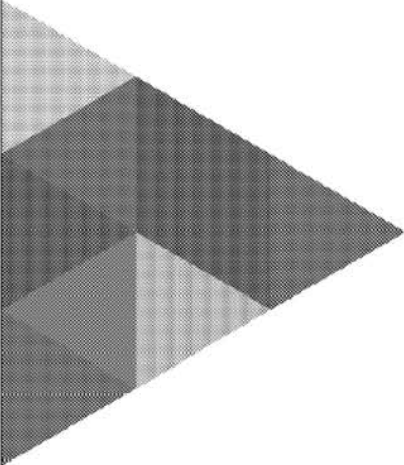
Defining product positioning relative to competition



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Communication Platform

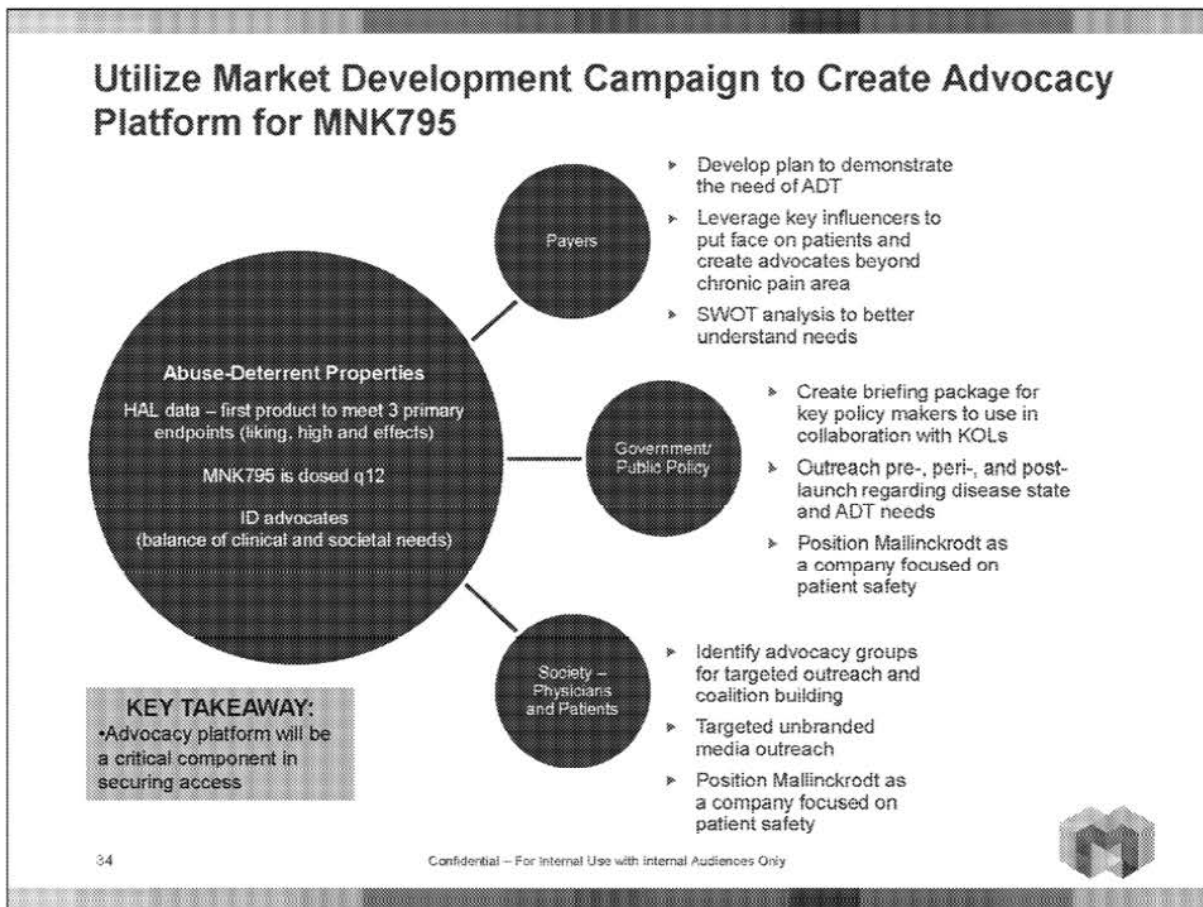
Communication Platform
Elevate the unmet need(s) in the acute pain space

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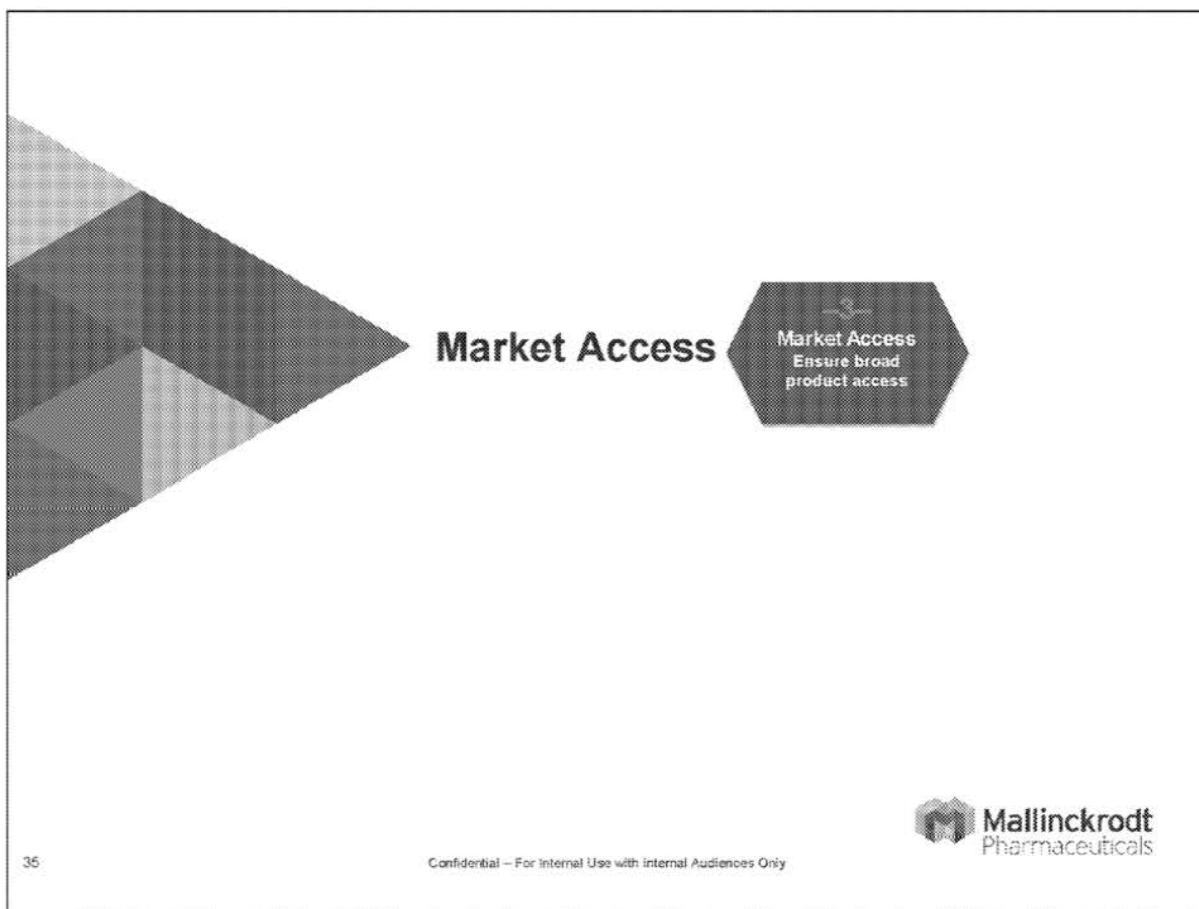
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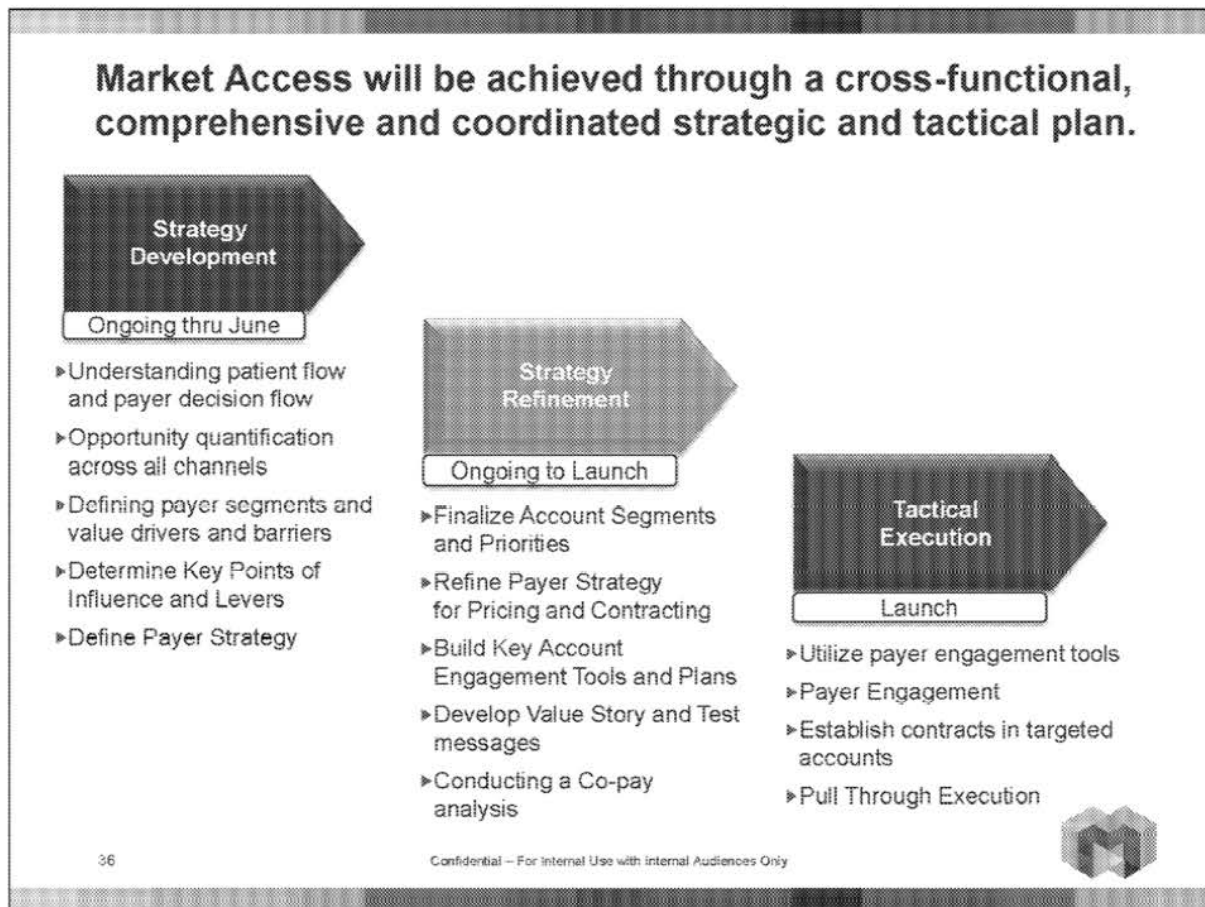
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The process we are undergoing to establish our strategy and build our executional plan is based in market excellence principles.

We are conducting this work in concert with the brand team to ensure consistency and alignment with our strategic direction and messaging.

In quantifying the opportunity, we have found that the commercial payer is likely the most "open" channel for us at launch, with about 75% of plans placing 795 at Tier 3 with no restrictions.

We have built a model that will help us conduct trade-off analysis as we finalize our account segments and prioritize them for engagement.

We are examining the need for co-pay assistance programs to support patient affordability.

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Emerging Managed Care Strategy

Maximize the value of MNK795, leveraging the clinical and potential societal benefits to secure unrestricted access

Key Messaging Components for Product

- Establish value in **effective/appropriate pain management of targeted patients** with moderate to severe acute pain, and reducing abuse potential.
- Public policy and advocacy is needed to support the abuse potential story.
- Align key **MCO product messaging with commercial/medical strategy**
- **Conduct additional studies** to further strengthen product messaging

Payer Prioritization

- Prioritize plans by payer segment, size, and drug review cycle /policy and willingness to grant preferred coverage w/o hard edits
- Create clinical and economic platform that elevates negotiations beyond price

Pricing and Contracting

- Price at parity to branded opioids (WAC \$6.00-\$8.00) & **selectively contract with priority plans to ensure Tier 3 with no hard edits**
- **Selectively contract with key Medicare plans for preferred coverage**

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Our message to payers needs to consist of discussion around burden of illness, burden of treatment, societal burden, public policy around the use and abuse of opioids.

We will prioritize our accounts using many variables including their willingness to cover our product without hard edits. It will be critical that we create a platform to transfer knowledge of this brand to appropriate MCO pharmacy and medical directors at our priority accounts.

Focus mostly on Commercial at launch, working strategically with some Medicare plans depending on initial coverage decision (like to not be covered) their timeline for review and decisions and willingness to allow us to contract away edits.

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MNK 795 Value Proposition – DRAFT

MNK795 provides fast-acting and long-lasting relief for patients suffering from moderate to severe pain, while reducing the potential for abuse

- <1 hour onset with sustained duration, providing the efficacy traditionally associated with Percocet without the peaks and troughs seen with immediate release products
- 12-hour pain relief resulting from proprietary, gastro-retentive technology which supports bi-modal, bi-phasic, controlled-release

Efficacy

- Well tolerated
- Adverse events comparable to other opioids in class
- No accumulation – oxycodone / APAP is cleared at 12 hours
- Does not dose dump with alcohol
- No food effect

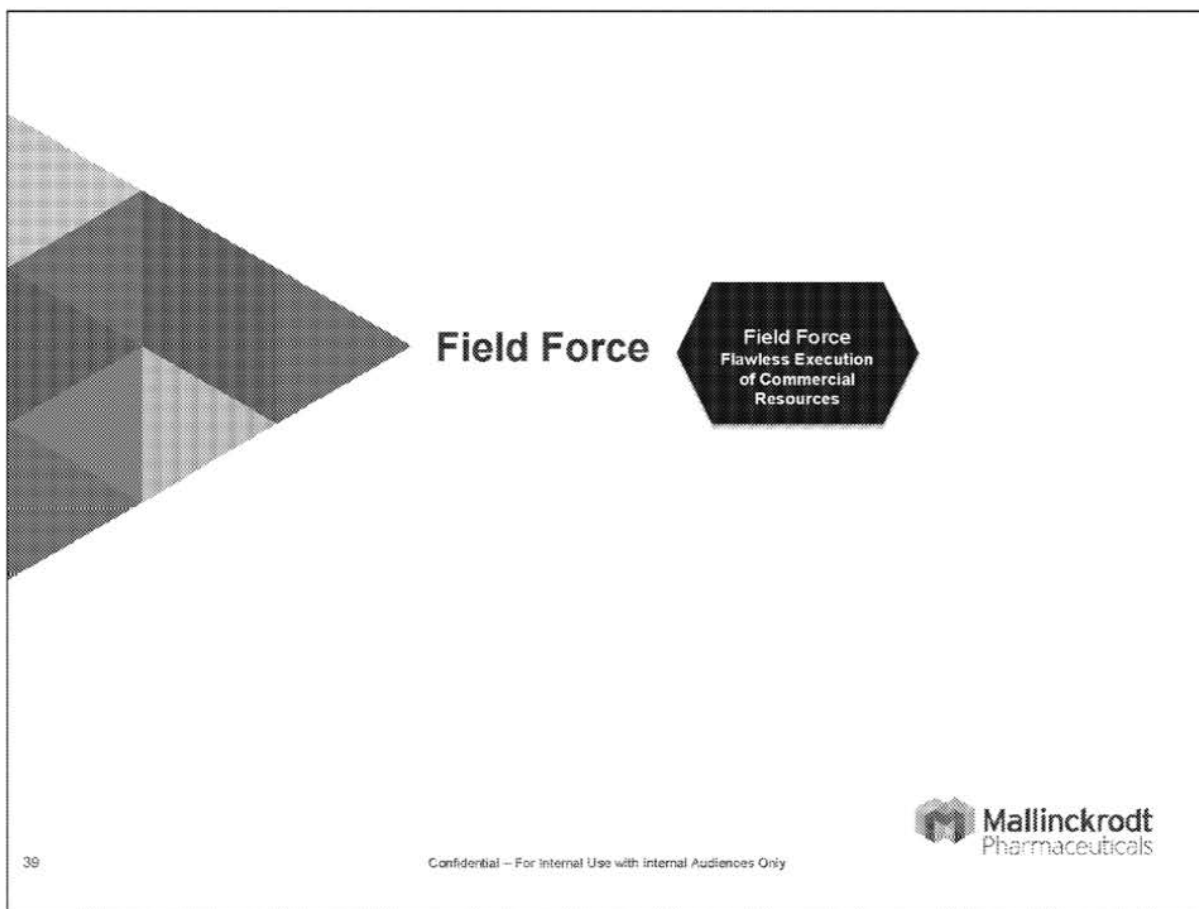
Safety

- Significantly lower patient disposition for "drug liking" and "drug high" compared to Percocet in both tampered and un-tampered forms
- Presents challenges for the abuser when tampered – mixing of long-acting and immediate release excipients results in conversion of drug release to long-acting, eliminating immediate release phase of drug

Social Impact

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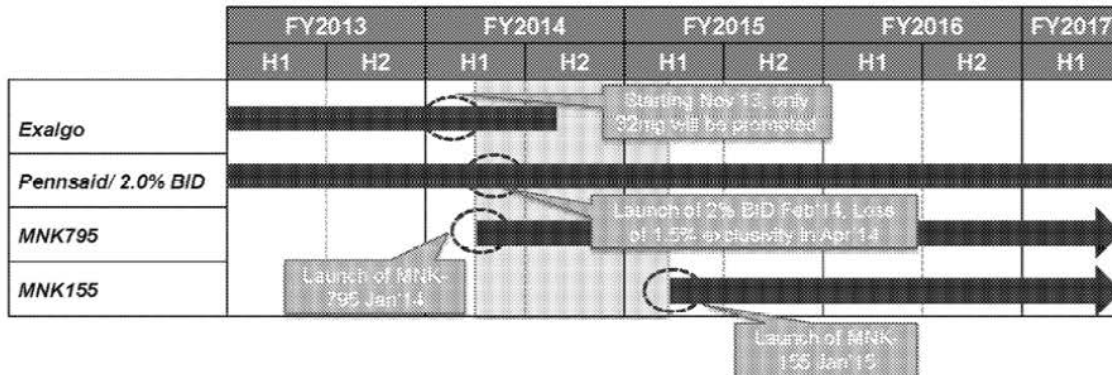




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The optimal sales force size and structure is contingent upon the products to be promoted

- Ask: fixed or variable sales force size
 - Will we change # of resources regularly or flex promotional mix (PDEs per product, detail positions, targets covered, etc. for different products) to manage within a given size?



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The optimal size of the sales force will depend upon two key assumptions:

- Percent of the market that must be covered
- Appropriate frequency that physicians must be detailed to drive share

Further refinement based on multi-level segmentation

The office-based prescriber audience is large. We could reach 50% of the MNK795 market with 450 sales representatives or 65% with 740.

Prescribers & Sales Force Size by Decile for MNK795

	Prescribers		% Market Covered	Sales Force Size by Frequency Model			Expected 2016 Revenue by Frequency Model		
	Total	Cumulative		3/2/1	2/1	1	3/2/1	2/1	1
MNK795 Decile	10	1,422	10%	27	18	9	?	\$80	?
	9	4,352	20%	109	73	36	?	\$162	?
	8	7,844	30%	241	161	80	?	?	?
	7	9,637	40%	395	284	142	?	\$339	?
	6	13,539	50%	561	450	225	?	\$433	?
	5	13,079	60%	787	620	338	?	\$530	?
	4	25,255	70%	1,024	856	496	?	\$631	?
	3	37,512	80%	1,376	1,091	730			
	2	63,864	90%	1,775	1,490	1,129			
	1	256,535	100%			2,733			
Total	437,254	437,254							

With 450 FTEs Mallinckrodt can reach 40,000 physicians and 50% of the market for MNK795 and reach an expected peak revenue of \$433M in 2016

Assessment of revenue by market reach ongoing to determine optimal sales force size (Segmentation/STEP).

Note: Numbers in each cell indicate the total number of prescribers in each segment. Excludes Veterinarians, Pediatricians, and Dentists

PENNSAID 2% would be in 2nd position where appropriate and in 1st position with an additional 2,000 to 3,000 targets specific to the topical NSAID market. Revenue projections assume market share is a constant while market reach changes in the different size scenarios (bridged from strat-plan forecast, to be revalidated).

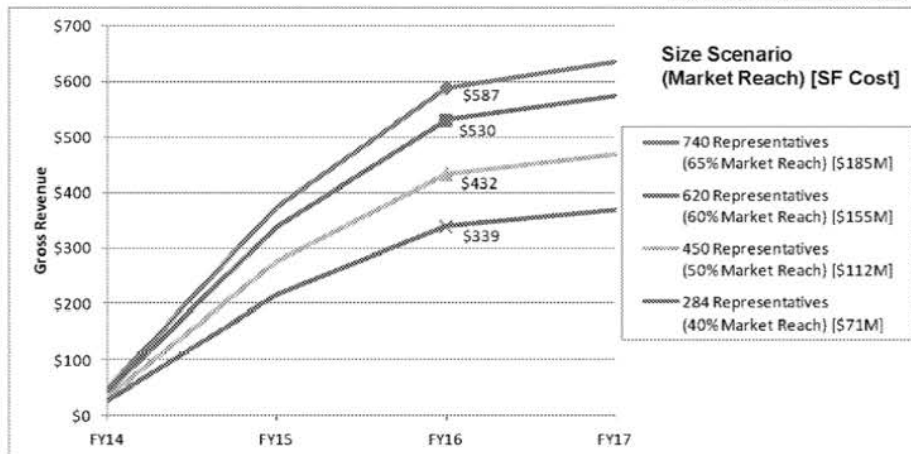
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Why they need to be this big: what you cover

A larger sales force is required to drive the top-line but a smaller sales force is more efficient.

Forecast revalidated
with STEP



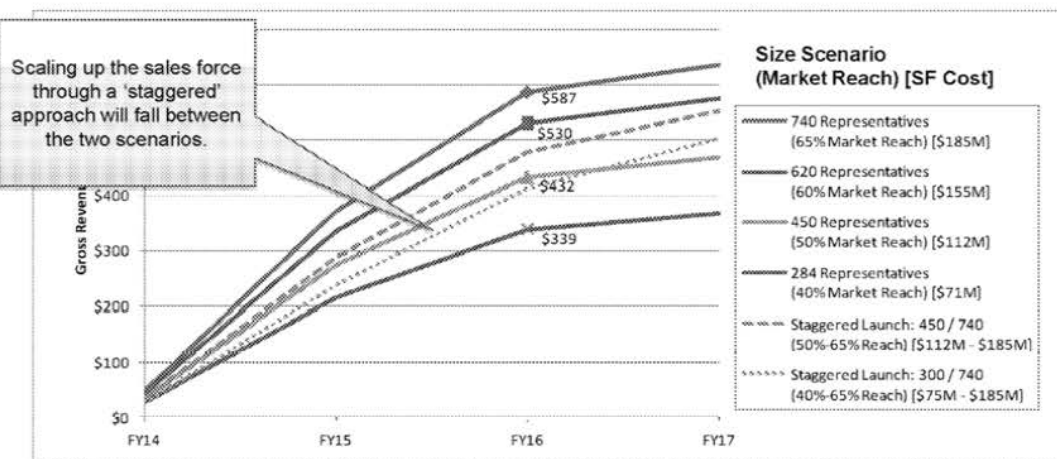
- Efficiency: Expected peak revenue per territory ranges from \$800k with 740 representatives to \$1,200k with 284 representatives.
- Revenue projections based upon current forecast and interpolated based upon changes to market reach—market share is a constant among the reached prescriber universe.

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A larger sales force is required to drive the top-line but a smaller sales force is more efficient

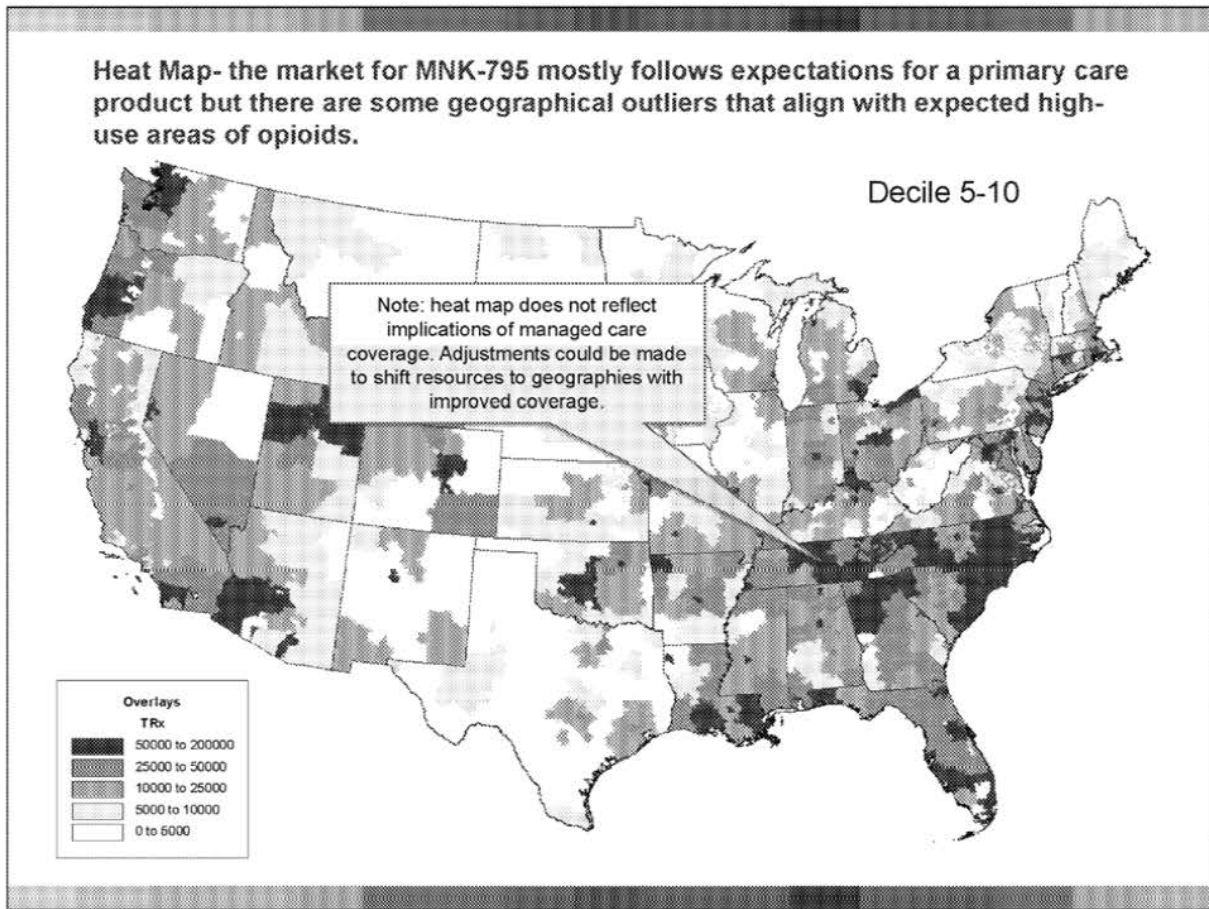


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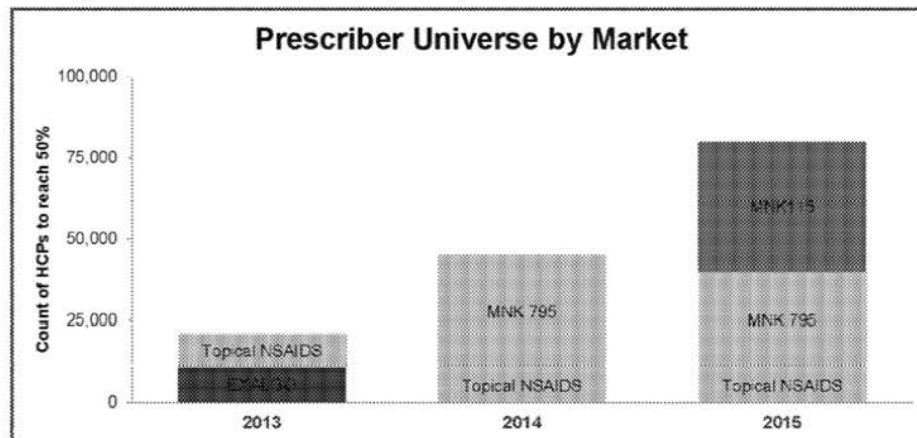
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Alternative GTM Sales Force Models

The target audiences ramp-up quickly.



Option 1: Staggered Investment

► Traditional CSO

A traditional CSO relationship provides a nimble option for sales force sizing but with a traditional cost model.

Option 2: Invest Early

► Revenue Share CSO

Revenue sharing and co-marketing relationships are cost-effective solutions to create a large sales presence.

► Strategic Alliance (e.g. Lilly, J&J, Pfizer, Forest)

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There are several options for building a sales organization to support MNK-795, each offering a unique set of opportunities and challenges.

▶ <u>Traditional CSO</u>	▶ <u>Revenue Share CSO</u>	▶ <u>Strategic Alliance Partner</u>
<p>▶ Pros</p> <ul style="list-style-type: none"> ▶ Flexibility and speed 	<p>▶ Pros</p> <ul style="list-style-type: none"> ▶ Flexibility and speed ▶ Downside risk mitigated ▶ Potential for larger footprint 	<p>▶ Pros</p> <ul style="list-style-type: none"> ▶ Downside risk mitigated ▶ Potential for larger footprint ▶ Positive Street Perception ▶ Infrastructure & support
<p>▶ Cons</p> <ul style="list-style-type: none"> ▶ Costs comparable to traditional sales force models ▶ Investment is "at-risk" ▶ Perception for co-promotes ▶ Limited history of success in launching big products 	<p>▶ Cons</p> <ul style="list-style-type: none"> ▶ Upside Risk ▶ Perception for co-promotes 	<p>▶ Cons</p> <ul style="list-style-type: none"> ▶ Upside Risk ▶ Risk of Bureaucracy and slower decision making ▶ Loss of Control ▶ May limit tactics (CIAs)

Flexibility: ability to expand and contract the size of the sales force in response to market events.

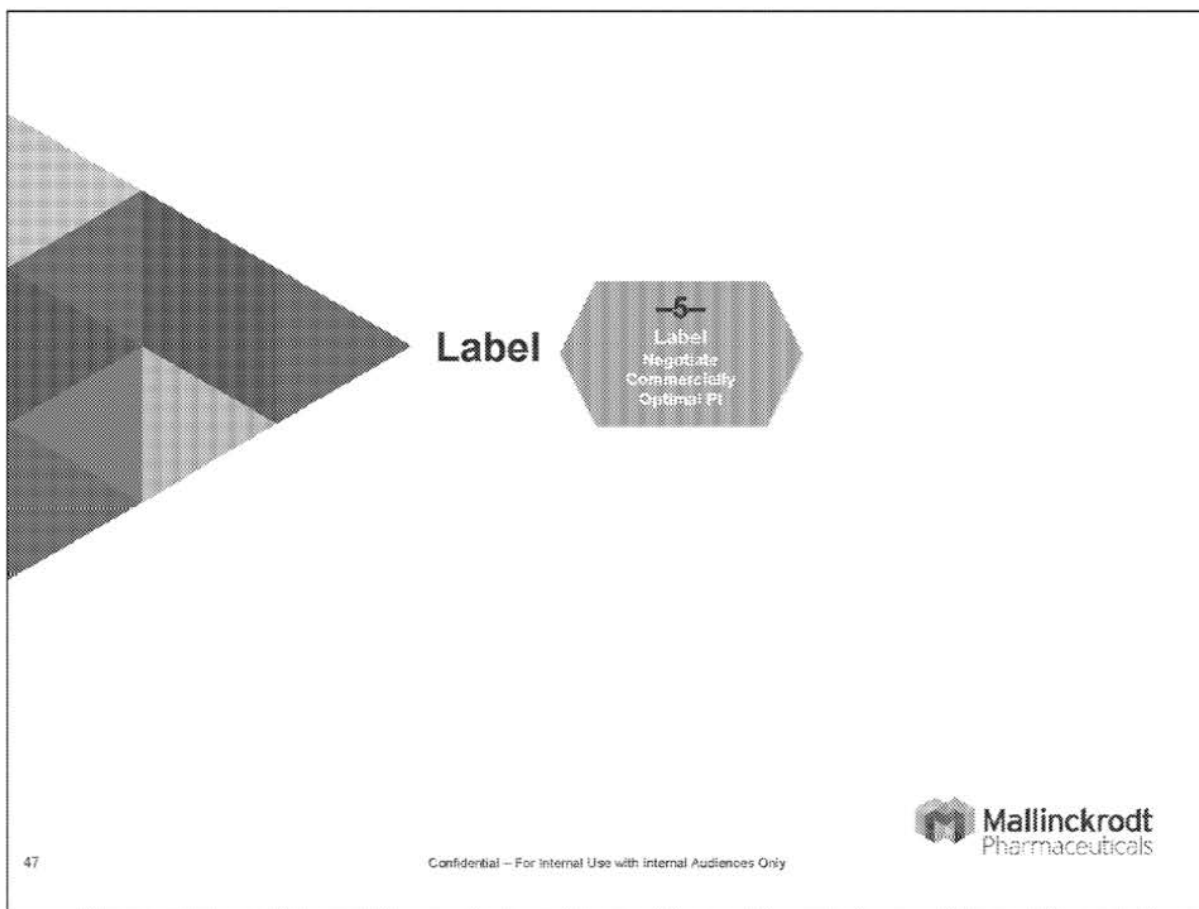
Downside risk: product revenues are do not meet expectations and do not cover the sales force investment

Upside risk: revenues exceed expectation but must pay a percentage to a partner.

Perception for co-promotes: if CSO representatives are not legally viewed as 'employees' the options to leverage their capacity in future co-promotes and BD&L deals is limited.



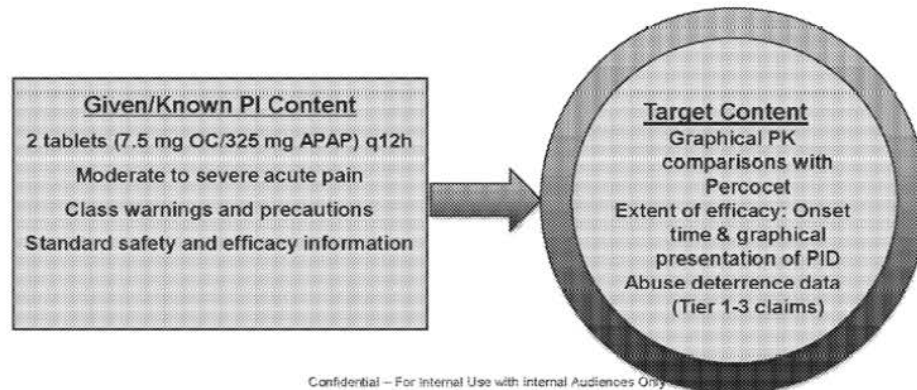
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Commercial Strategy Drives Label Development and Negotiation

- ▶ Label is foundation for commercial success, and medical and scientific support
- ▶ Combination of class/reference listed drugs and MNK795 specific information
- ▶ High-caliber team convened to develop optimal" label
- ▶ Built consensus around sections of label with highest value/ability to influence
- ▶ Ensuring success by prioritizing claims to inform negotiations



Label is the foundation for both commercial success and medical/scientific support

Label will be a combination of class/reference listed drugs and MNK795-specific information

Team of internal and external experts established to develop an "optimal" label

Discipline approach to identify and assess possible label claims

Understand potential approval scenarios

Understand commercial value of label claims; advantages/disadvantages of data in label

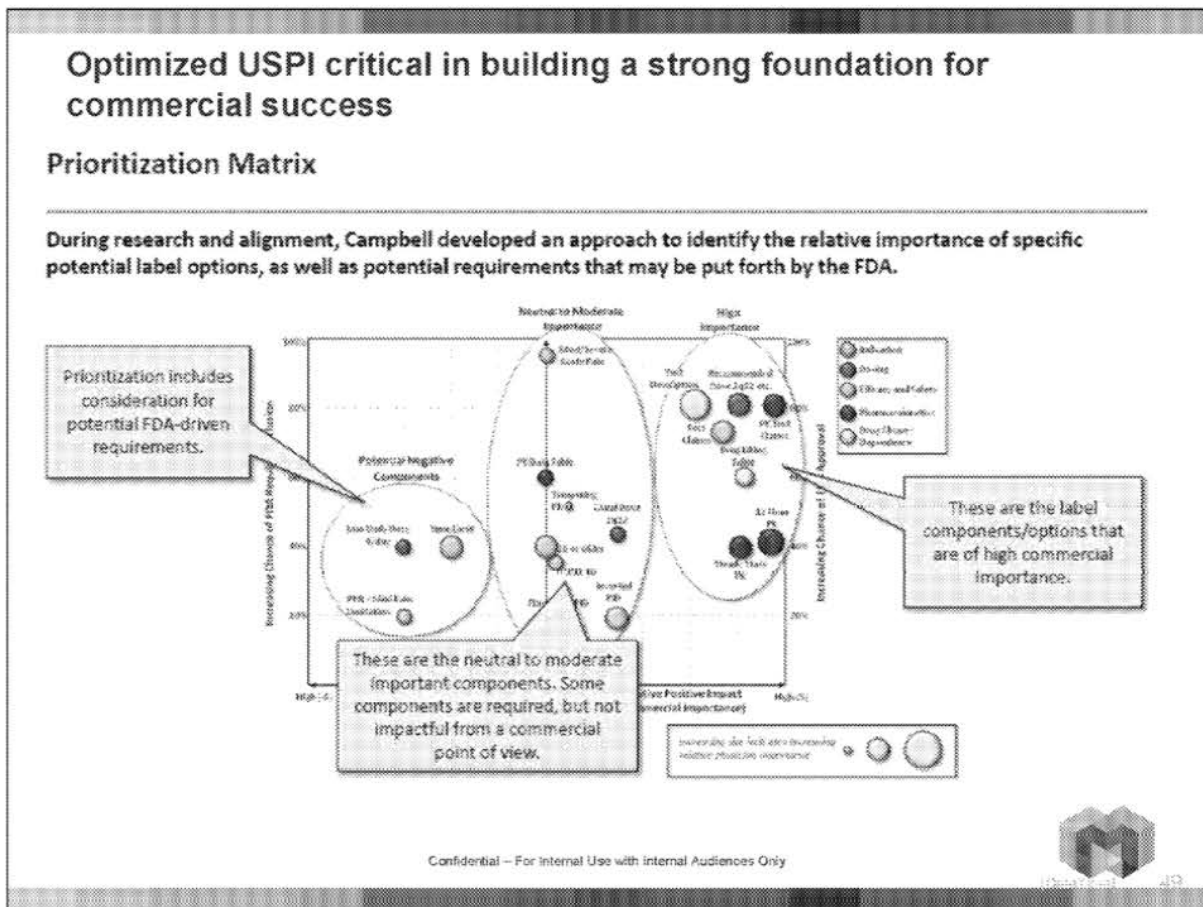
Qualitative and quantitative market research to validate value of claims; inform negotiating strategy

Built consensus around sections of label highest value/ability to influence; optimized label submitted

Established prioritized list of label claims to inform negotiations; ensure success

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Disciplined approach to label optimization initiative

Identified label claims perceived to have the highest value to commercial success identified

Determined relative importance of each claim:

Increasing Chance of FDA Requirement

Increasing Chance of FDA Approval

Positive/Negative Impact to Commercial

"Sized"/Quantified importance to physicians

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MNK795 Governance and Organizational Structure

Executive Leadership Team

Leadership Endorsement

- Process Oversight
- Approval of high-level decisions
- Issue resolution
- Resource prioritization & allocation

Executive Leadership Team:

- | | |
|---------------------------------------|------------------------------|
| • M. Trudeau, CEO | • M. Harbaugh, CFO |
| • S. Carchedi, NA President | • I. Watkins, HR |
| • M. Giuliani, CSO | • M. Fischer, Communications |
| • T. Smith, CMO | • P. Edwards, Gen. Counsel |
| • S. Merrick, International President | • T. Berry, Manufacturing |

Core Launch Team

Cross-Functional Core Team

- Drive and lead launch planning process
- Ensure alignment and coordination of launch activities
- Communicate needs/support with leadership

Cross-Functional Leadership:

- | | |
|-------------------|----------------------|
| • Marketing | • Business Insights |
| • Medical Affairs | • Regulatory |
| • Managed Markets | • Manufacturing |
| • Communications | • Project Management |

Working Teams

Promotional
Communications

Field Force
Preparedness

Managed
Markets

Product
Availability and
Trade

Medical Affairs
and Scientific
Communications

Government
Affairs and
Advocacy

Cross-Functional Working Teams

- Develop plans and implement tactics
- Identify gaps in implementation & take action
- Develop recommendations for approval

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Work Team Project Scope/Objectives Aligned in Support to Key Commercialization Goals

Promotional Communications

Differentiate MNK 795 from the competition by ensuring the essence of the brand is captured, framing the market into actionable and meaningful segments and identifying specific customer behaviors to drive adoption

Field Force Preparedness

Prepare the sales force to best capitalize on opportunities to differentiate MNK 795 by developing a physician and pharmacy centric value message, and executing an interactive training plan. Structure and align the sales force to ensure they are positioned to increase awareness of MNK 795 with both high and moderate volume opioid prescribers through specialty targeting and the development of a call plan

Managed Markets

Ensure rapid uptake by establishing a competitive price and developing a contracting strategy that provides broad access across all appropriate channels

Product Availability and Trade

Ensure MNK 795 is stocked in the appropriate number of pharmacies through the launch period by the development and execution of sound trade plans, an accurate supply forecast, and a thorough field sales pull-through strategy

Medical Affairs

Ensure rapid uptake of MNK 795 at launch through increased awareness among opioid prescribers utilizing publications and key congresses to shift the paradigm relating to the perception of how to treat and define pain within the acute pain landscape

Government Affairs and Advocacy

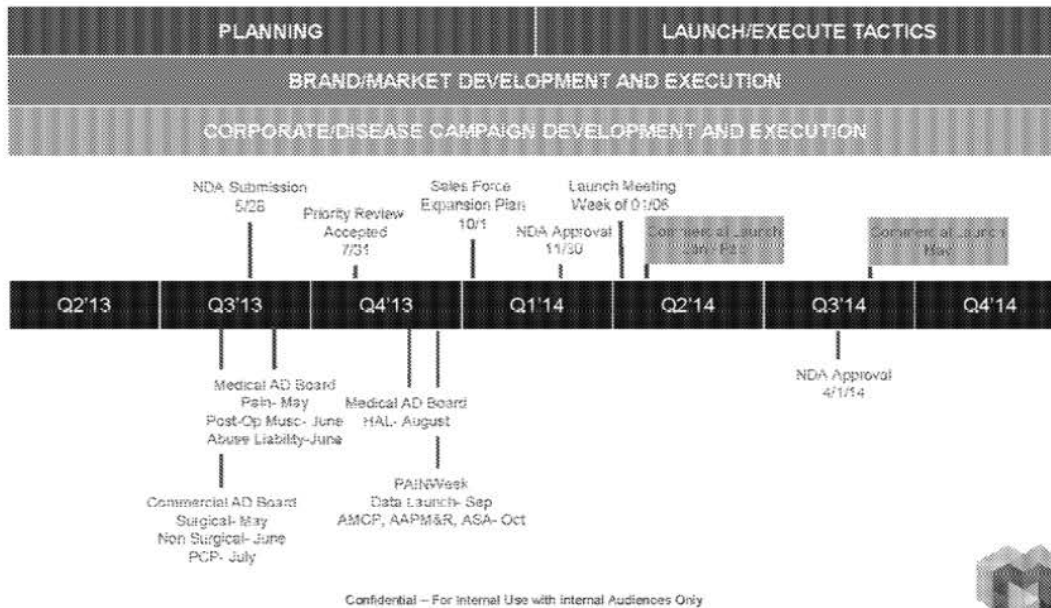
Encourage safe and appropriate use of opioids (including MNK795) through C.A.R.E.S. Alliance educational tools and activities. Utilize new and existing relationships to increase awareness of important issues surrounding opioid abuse and consequences of inappropriate prescribing. Understand and capitalize on the value of MNK795 within the Government and Regulatory landscape

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High Level Timeline and Key Pre-Launch Milestones

- › Two FDA review scenarios: Priority Review (6 months) and PDUFA (10 months)
- › Notice of granting Priority Review by mid-July; planning for January 2014 launch
- › Investment needs and timing is required, irrespective of review scenario



* If retain >30% of base sales measured 3 mths after LOE & mthly thereafter

** Includes: Pain Franchise Campaign, OV Tech Campaign, & commercial development efforts

MNK795 Launch Expenses Based upon Priority Review – Jan 2014 Launch

XARTEMIS Commercial Launch Expense

	FYTD Q3 FY13						Q4 FY13						Q1 FY14						Total Launch Expense						
	Mktg & Sales	Medical Affairs	Ops.	Global Mktg.	Managed Mkts	Port. Mgmt	Mktg & Sales	Medical Affairs	Ops.	Global Mktg.	Managed Mkts	Port. Mgmt	Mktg & Sales	Medical Affairs	Ops.	Global Mktg.	Managed Mkts	Port. Mgmt	Mktg & Sales	Medical Affairs	Ops.	Global Mktg.	Managed Mkts	Port. Mgmt	Total
Market Access					\$ 400	\$ 500		\$ 540			\$ 1,286	\$ 225					\$ 445			\$ 540			\$ 2,133	\$ 775	\$ 3,446
Market A&P	\$2,698			\$ 725			\$4,329			\$ 265			\$ 5,097						\$12,124			\$ 990			\$ 13,114
Selling													\$13,600						\$13,600						\$ 13,600
Medical Affairs ^A		\$1,172						\$1,263					\$2,995						\$5,430						\$ 5,430
Manufacturing ^{B,C}			\$ 331																		\$331				\$ 331
Total ^D						\$5,826						\$7,958						\$22,137							\$ 35,921

A: Speaker Bureau, REMS, ISR & Publications
B: Does not include \$1.95MM of Capital Costs or associated Depreciation
C: Excludes \$532K of initial stability costs (R&D expense)
D: Excludes R&D expense of \$24.3MM
E: Includes ~\$4.1MM of implementation costs provided by Shared Services (IT & Training)

XARTEMIS Commercial Launch Expense

	Q2 FY14					Q3 FY14					Q4 FY14					Total Post Launch FY14 Expenses				
	Mktg & Sales	Medical Affairs	Ops.	Global Mktg.	Managed Mkts	Port. Mgmt	Mktg & Sales	Medical Affairs	Ops.	Global Mktg.	Managed Mkts	Port. Mgmt	Mktg & Sales	Medical Affairs	Ops.	Global Mktg.	Managed Mkts	Port. Mgmt	Total	
Market Access					\$ 100													\$ 100	\$ 100	
Market A&P	\$2,242						\$3,352						\$ 2,327				\$ 7,781		\$ 7,781	
Selling	\$9,458						\$9,458						\$ 9,458				\$26,443		\$ 26,443	
Medical Affairs ^A		\$2,545						\$2,545					\$2,545				\$7,635		\$ 7,635	
Manufacturing ^{B,C}			\$ 259														\$ 259		\$ 259	
Total ^D						\$4,734							\$15,105				\$14,310		\$ 44,238	

**Selling expenses are incremental costs associated with increasing Sales Force size(+210 HC); excludes costs associated with current sales force (211 HC).

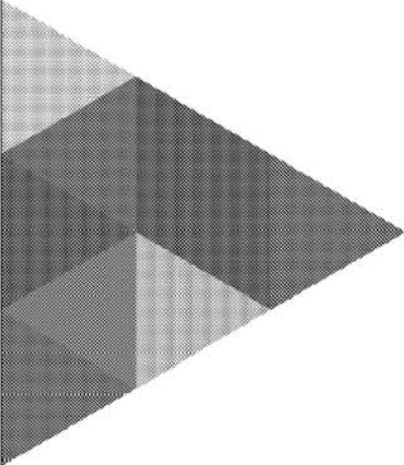
A: Speaker Bureau, REMS, ISR & Publications
B: Does not include \$34.5MM of Capital Costs or associated Depreciation
C: Excludes \$542K of commercial stability costs (R&D expense)
D: Excludes R&D expense of \$8.1MM

Total FY13 - \$13.8MM
Total FY14 - \$66.4MM

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Sizing the Revenue Opportunity

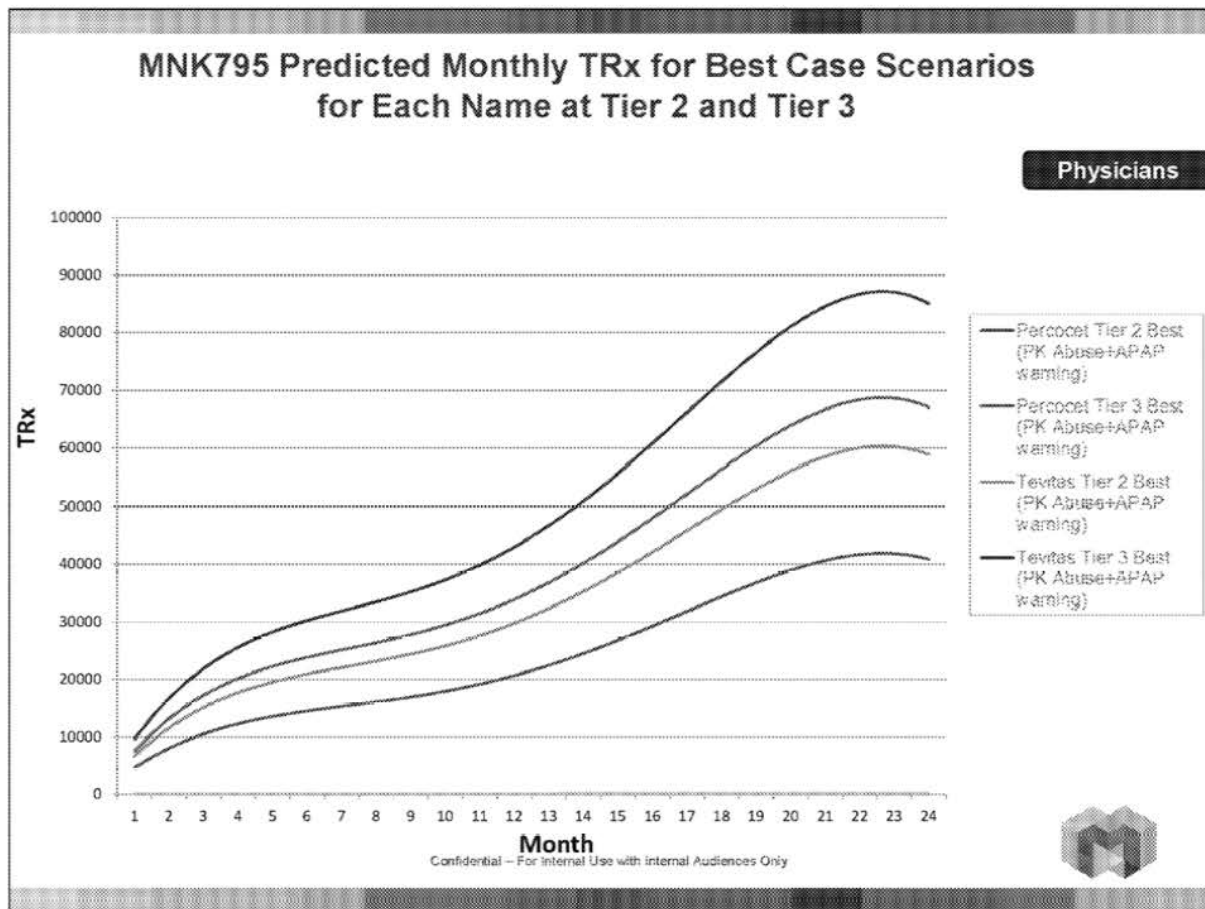
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Executive Summary

**MNK-795 will drive stakeholders to rethink acute pain treatment and abuse deterrent properties.
Demonstrate the unmet need around acute pain by humanizing the issue.
Establish MNK 795 as a new standard in acute pain management.**

➤ **MNK-795 Has ~\$250M US Potential Peak in the Opioid Market**

- One of the first new brands in the acute pain combination opioid market in the past 20 years
- Controlled-release analgesia and abuse deterrence properties

➤ **The Acute Pain Market Is Ripe with Opportunity**

- The opioid combination market is poised for innovative options
- Global pain market over \$20B; The largest segment is the acute pain segment
- Few branded competitors and limited number of drugs in development

➤ **MNK-795 Addresses the Market Needs**

- Quick onset, relief within 30 minutes of dosing
- Controlled release, which helps patient's sleep through the night without waking
- Abuse deterrent properties, which meet the FDA guidance; label to include data

➤ **MNK-795 Will Give HCPs and Allied Stakeholder's Reason to Pause**

- 30+ year habitual prescribing will be challenged due to recognition / appreciation to **assess and treat the patient and greater abuse problem**, as opposed to treating the pain (eg, Percocet 1-2 tabs, q4-6h)

➤ **Mallinckrodt Will Realize Vision as the Market Leader in Pain Management**

- More than 20 years experience in marketing pain drugs and a track record of successful collaborations

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